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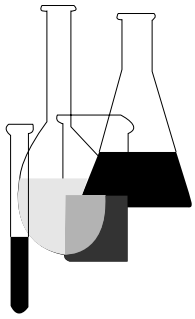
Residue Chemistry Test Guidelines

OPPTS 860.1500
Crop Field Trials



"Public Draft"

INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

Public Draft Access Information: This draft guideline is part of a series of related harmonized guidelines that need to be considered as a unit. *For copies:* These guidelines are available electronically from the EPA Public Access Gopher (gopher.epa.gov) under the heading ‘‘Environmental Test Methods and Guidelines’’ or in paper by contacting the OPP Public Docket at (703) 305–5805 or by e-mail: guidelines@epamail.epa.gov.

To Submit Comments: Interested persons are invited to submit comments. By mail: Public Docket and Freedom of Information Section, Office of Pesticide Programs, Field Operations Division (7506C), Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person: bring to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. Comments may also be submitted electronically by sending electronic mail (e-mail) to: guidelines@epamail.epa.gov.

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OPPTS 860.1500 Crop Field Trials

(a) **Scope.**

(1) **Applicability.** This guideline is intended to meet testing requirements of both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C 135 et seq.) and the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301 et seq.)

(2) **Background.**

(i) The source materials used in developing this harmonized OPPTS test guideline are OPP guidelines 171–4k, 171–4c, 171–12a–d (see reference in paragraph (l)(1) of this guideline). In addition, paragraphs (l)(2) through (l)(7) provide references for background materials published subsequently to the OPP guidelines. These include, among other topics, guidance on conduct of residue studies and data reporting guidance.

(ii) This OPPTS guideline should be used in conjunction with OPPTS guideline 860.1000, Background, which provides general information and overall guidance for the 860 series on Residue Chemistry. Topics discussed in this 860.1500 guideline include: Purpose (paragraph (b); General considerations (paragraph (c)) Design of residue experiments (paragraph (d)); Number and location of domestic crop field trials for establishment of residue tolerances (paragraph (e)); Aspirated grain fractions (paragraph (f)); Test method (paragraph (g)); Data reporting for crop field trials (paragraph (h)); Data reporting for specialty applications (paragraph (i)); Data reporting for postharvest fumigation (paragraph (j)); Data reporting for post harvest treatment except fumigation (paragraph (k)); References (paragraph (l); and Appendix A containing tabular and graphical materials used in determining requirements for number and location of crop field trials.

(b) **Purpose.** Crop field trials are conducted to determine the magnitude of the pesticide residue in or on raw agricultural commodities (RACs) and to reflect pesticide use patterns that could lead to the highest possible residues. The pesticide must be applied at known application rates and in a manner similar to the use directions intended for the pesticide label. Data are normally required for each crop or crop group for which a tolerance and registration is requested and for each raw agricultural commodity derived from the crop.

(c) **General considerations.** The residue field experiments consist of examination of raw agricultural commodities for residues of the pesticide chemical after treatment corresponding to the uses proposed in Section B of a petition. Residue investigations should be specifically designed so as to circumscribe the total residue picture. Data should be available to show whether residues occur on any plant parts that may beused in foods or feeds. Use on rice may necessitate residue data for water, shellfish,

fish, and irrigated crops when water from the rice field is diverted to such uses.

(1) **Residue(s) determined.**

The purpose of field experiments is to quantify by chemical analyses the terminal residues of concern that have been previously demonstrated in the plant metabolism studies. The ‘‘total toxic residue,’’ as defined in OPPTS guideline 860.1300, Nature of the residue - plants, livestock, should be determined by the analytical method of choice. In some cases, it may be necessary to employ more than one analytical method to determine the ‘‘total toxic residue.’’ Terminal residues in some commodities may differ from those found in other commodities, e.g., residues in meat or milk may differ from those in plants. In cases where determination of bound residues or minor metabolites require separate analysis or unduly increase the cost of processing residue samples, not all samples must be analyzed for these components. However, enough of the samples must have been analyzed for these components to allow estimation of the ratio of these components to the parent compound.

(2) **Sampling.**

The samples taken should be of the whole raw agricultural commodity (RAC) as it moves in interstate commerce. For some crops there may be more than one RAC derived from the crop. For example the RACs for field corn include the seed, fodder and forage. Table I of OPPTS guideline 860.1000, Background, contains a list of the RACs derived from each crop. The sample should not be brushed, stripped, trimmed, or washed except to the extent that these are commercial practices before shipment, or to the extent allowable in Section 180.1(j), Code of Federal Regulations or the Pesticide Assessment Manual (PAM) (see paragraph (l)(8)). In the enforcement program, produce is examined for residues on as ‘‘as is’’ basis, regardless of whether it meets any Federal or State quality grading standards with respect to washing, brushing, or number of wrapper leaves retained. Because certain crops (cabbage, celery, and lettuce) may be shipped without having been stripped or trimmed, samples of these crops should be untrimmed for determining tolerances; only obviously decomposed outer leaves should be removed. Data on trimmed and/or washed samples may be generated at petitioner’s option for use in risk assessment. The preparation of each sample prior to analysis should be indicated.

Samples should be collected to reflect the various raw agricultural commodities that might be marketed separately, consumed or fed at various times. For example, in an early post-planting use on winter wheat, the green plant should be sampled at the time it might be foraged and cut for hay, the mature wheat grain should be sampled, and the dried straw

should be sampled. Table I of OPPTS guideline 860.1000 includes a list of the various RACs that should be analyzed.

The sample taken from a field should be representative of all portions of the crop from the field. Thus, there should be a valid statistical basis for sampling. Standardized procedures, such as the use of the Latin squares for a forage crop, selection of tree fruits from the upper, middle, and lower levels of opposing quadrants of the tree; the use of grain triers for the taking of core samples of commodities in bulk quantities; and sample reduction by quartering of replicate samples from a field are desirable. It is preferable to have additional field site data rather than replicate data from within a field if only a limited number of samples are analyzed. More detail on numbers of samples are provided in section (e)(2)(iv) of this guideline.

Accepted procedures for maintaining sample integrity should be followed after taking the sample. Normally samples should be frozen as soon as possible and kept frozen until analyzed. Information should be furnished on how samples are shipped and stored until analyzed. If samples are likely to be held in storage, storage stability data should be obtained (see OPPTS guideline 860.1380).

(d) **Design of residue experiments.**

(1) **Field studies.**

The field experiments should be designed specifically to yield residue data, not merely as an adjunct to field performance (efficacy) tests. Field experiments must reflect the proposed use with respect to the rate and mode of application, number and timing of applications, and formulations proposed. Because of differences observed in residue levels resulting from ultra low volume (ULV) and aerial applications, these too should be represented unless the proposed label specifically prohibits such application methods. Some crops may be grown under conditions of little or no rainfall, such as lettuce grown in the Imperial Valley of California. Such areas need to be included in field trial programs. More details on number and location of trials to be conducted are provided in paragraph (e)(2)(iv) of this guideline.

For significant food/feed crops, the field experiments must also provide for residue dissipation or decline studies in which samples are taken at intervals during the period from the last application of the pesticide to normal harvest. The data obtained should indicate the pattern of uptake of the pesticide and its decline. When presented graphically, these data are useful in determining a preharvest interval if one is needed. More details on residue decline data appear in paragraph (d) of this guideline.

(2) **Fumigation areas.**

In addition to fumigation treatments at the proposed use conditions, treatment at exaggerated rates is desirable. The studies should adequately represent those commodities which might be treated, including oily foods (peanuts, butter), and high surface area foods (flour), and types of packaging allowable under the directions for use. The studies should reflect the effect of parameters such as times of exposure, dosage, temperature, pressure, geometry and airtightness of the container upon residue levels. The effect of aeration time and procedure upon residue reduction should be demonstrated.

(3) **Slow-release encapsulated formulation uses.**

The use of slow-release encapsulated formulations may lead to higher residues than conventional formulations. Thus, if use of a slow-release formulation is proposed, residue data reflecting this formulation will be required. Data showing that the analytical method detects any active ingredient remaining in the encapsulating material at the time of analysis is required. The registrant should consult the Agency chemists and toxicologists concerning whether residue data on the encapsulating wall material are needed. The general criteria used by the Agency is that if the encapsulating material is an inert polymer and is not absorbed from the gut, then residue data are not required. For polymers not previously cleared, this requires a radiolabeled encapsulating material feeding study with rats showing essentially 100% excretion of activity, with no residual activity in tissues. Data on the residue levels of the encapsulating material will not be required for uses involving application before edible parts form.

(e) **Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances.**

(1) **Summary.**

(i) **General.** This section provides guidance on the number and location of crop field trials. The number of trials required for a crop takes into account not only its production acreage, but also its dietary significance. All field trial programs **initiated in 1995 or later** should adhere to this guidance. If fewer trials than required in this section are submitted or if a certain region is not represented in trials conducted prior to 1995, judgment will be used to determine whether any additional data are needed. Factors such as the level of residues (i.e., how close to the limit of quantition (LOQ)) and the variability of residues in those trials that were conducted, and the available data for the pesticide on related crops will be considered. When the data fall seriously short, it may not be possible to establish a tolerance until the missing data are provided. In those cases where the data come close to the requirements in this document (e.g., one

too few field trials; lack of data from a region of relatively low production) or where the data sufficiently represent residues likely to be seen based on data for similar uses and professional judgment, the tolerance may be granted on a conditional basis.

(ii) **Definitions.**

(A) A ''**pesticide field trial site**'' is a geographically defined address/location within a country/region/state of a field, space, water body or other area in or on which a pesticide field trial is conducted. (In most cases this definition boils down to a site being one farm.) A site typically consists of several **plots** (areas of ground with defined boundaries on which a crop is grown), each of which receives a specified pesticide application regimen.

(B) A ''**pesticide field trial**'' entails one or more applications per growing season of a formulated pesticide product to a specified crop (or the soil) at one site following actual or simulated cultural practices. Such applications are usually in accordance with registered or proposed uses (or a fraction or multiple thereof in some cases) to provide treated commodity samples for estimating pesticide tolerances and/or dietary exposure to pesticides.

(C) ''**Sample**'' is a defined amount of individual agricultural commodity units (e.g., specific number of fruits or tubers; a set weight of grain; etc.) randomly selected from a plot which may be composited for pesticide analysis. (NOTE: As discussed in paragraph (v), tolerances will continue to be based on analyses of composite samples. In the future EPA may also require analyses of individual servings (e.g., one apple, one potato) to assess the dietary risk from acutely toxic pesticides. (This possible requirement will not be discussed further in this guideline.)

(iii) **Numbers of field trials.**

The actual **numbers of field trials** that will be required for a large number of crops are shown in Table 1 of Attachment 7 (''REQ #FT'' column). The required numbers of trials range from 1 to 20. Crops having large acreage and high consumption for the general population or infants will need up to 20 trials, whereas crops of <200 total U.S. acres will need only one trial. In each case these represent the number of *acceptable* trials reflecting the label use pattern (maximum rate, etc.) producing the highest residue. Trials which reflect other use patterns or which for some reason do not generate viable samples (e.g., crop failure) will not be counted. For the purposes of standardizing the number of field trials, it should be emphasized that in most cases (see next paragraph) these numbers represent the *minimum* that will be accepted to establish a tolerance (with the exception of crop group tolerances or uses resulting in no quantifiable

residues). Additional trials are always welcome and even encouraged by the Agency.

EPA has taken into consideration several major factors to determine the necessary numbers of trials and believes these numbers will be applicable in most cases. However, in limited circumstances the Agency may require additional trials or accept fewer trials than specified in Table 1. Any petitioner believing that fewer trials are adequate for a given crop will need to provide a convincing rationale. In such cases the Agency strongly advises petitioners to submit a protocol and rationale *before* initiating such trials. Likewise, any residue chemistry reviews requesting additional trials will include a justification as to the need for such data.

(iv) **Residue decline data.**

This document also gives more specific guidance for current residue decline requirements. **Residue decline** data will be required for uses where: (1) the pesticide is applied when the edible portion of the crop has formed *or* (2) it is clear that residues may occur on the food or feed commodities at, or close to, the earliest harvest time. The number of decline studies needed is one for crops requiring 5–12 total trials and two for crops requiring 16–20 total trials. These studies are included in the 5–12 or 16–20 total trials (i.e., not ‘‘in addition to’’ these numbers of trials). For a given pesticide additional decline studies will not be required crop by crop if studies on representative crops (tree fruit, root crop, leafy vegetable, grain, and fruiting vegetable) indicate residues do not increase with longer preharvest intervals.

(v) **Compositing of samples.**

Two independently composited **samples** of treated commodity should be collected and separately analyzed in each field trial. These two samples may be taken from the same plot. An exception to these guidelines is crops requiring only 1–2 trials; for these crops four samples (one each from four separate plots (2 at 1x rate, 2 at 2x rate)) will be needed for each trial. In all cases Codex guidelines on minimum sample sizes should be followed (Attachment 8). A control crop sample should also be collected from each crop field trial site for analysis.

(vi) **Crop grouping.**

The numbers of trials in Table 1 of Attachment 7 are based upon each crop being the only one within its crop group for which a tolerance is requested. In the case of **crop group tolerances** for which there are at least two representative crops, the number of trials can be reduced by 25% for those representative commodities that need ≥ 8 trials when requested

individually (i.e., 20-15, 16-12, 12-9, 8-6). Table 2 shows the resulting numbers of trials needed for all crop groups in 40 CFR 180.41.

Since the Agency has recently finalized creation of **subgroups** within the existing crop grouping scheme, guidance on the number of field trials needed for the representative commodities in these subgroups is also provided in Table 3. These numbers of trials were determined on a case-by-case basis looking at the acreages and consumption of the representative commodities and of the whole subgroup. Similar principles were applied to crop ''groups'' established in 40 CFR 180.1(h) as specified in Table 4.

(vii) **Nonquantifiable residues.**

Provided metabolism data (on the crops of interest or related crops) or field trial data on related crops indicate quantifiable residues are not likely, a petitioner may elect to conduct 25% fewer trials for crops normally requiring ≥8 trials. However, if all of these trials do not show **residues below the method's limit of quantitation (LOQ),** additional trials will normally be required to bring the total number conducted up to the standard requirement. In addition to residues being below the LOQ, the following two conditions must be met for 25% fewer trials to be accepted: (1) the method has a sufficiently low LOQ (usually ≤0.01– 0.05 ppm) and (2) the trials still represent all significant regions of production.

The application of both 25% reductions discussed above (crop group and residues <LOQ) to a given crop will *not* be acceptable. In addition, neither 25% reduction will be applied to crops requiring ≤5 trials.

The numbers of trials in Table 1 of Attachment 7 are also predicated upon only **one formulation** type being requested for use on each crop. If additional types of formulation are desired, additional data such as side-by-side bridging studies may be needed as discussed in paragraph (e)(2)(x) of this document.

Some special considerations are also provided in this document for **early season uses on annual crops and spray volumes--ground versus aerial equipment.**

(viii) **Amended registrations.**

For **amended registrations** that involve significant changes in application rate or preharvest interval, the number of field trials required will normally be 25% less than that needed to establish an original tolerance, provided that the tolerance level is shown by the reduced number of trials to be adequate to cover the new use. However, if the reduced number of trials indicates that the original tolerance is inadequate, or if the original number

of trials was ≤5 or already included a 25% reduction (crop group or <LOQ), the number of trials needed for an amended registration will be the same as that for the original tolerance. On a case-by-case basis the Agency may require less additional data than described above for an amended registration.

(ix) **Location of field trials.**

With regard to the **location of trials,** the Agency agrees with the division of the country into 13 **regions** as proposed by NACA/IR-4 (see Attachments 9–10). This will allow greater flexibility in data collection for minor uses. For crops requiring >3 total trials, Table 5 shows suggested distributions of trials among these 13 regions. These distributions were developed using the concept that the number of trials per region should generally correlate with the percentage of the crop grown in that region. However, where possible, at least one trial should be included in each region having ≥2% of the national production.

(x) **Other considerations.**

The distributions of trials in Table 5 are not intended to be absolute requirements. Petitioners may wish to contact EPA regarding the suitability of alternative distributions of trials. To aid petitioners in determining distribution of trials, the production of numerous crops by region is specified in Table 6.

For crops requiring ≤3 trials, the data should represent to the extent possible a balance of the highest production areas, different geographic/climatic conditions, and/or major differences in varieties of the crop. At least one trial should be conducted in the region of highest production.

With respect to the distribution of multiple trials *within* a region, this should generally follow the relative production in the individual growing areas (states or counties as appropriate) of the region. However, the sites should also be sufficiently separated to reflect the diversity of the growing region.

To aid the Agency's review process, petitioners are requested to include a copy of the map in Attachment 9 showing the locations of all sites of acceptable trials in the volume of field trial reports for each crop.

Finally, separate guidance has been provided in Attachment 11 to address requirements for tolerances with **geographically restricted registrations and for 24(c) registrations.**

(2) **Detailed discussion.**

(i) **Background.**

In 1992 EPA conducted an analysis of residue chemistry studies that had been submitted in support of the reregistration of pesticides to determine the factors that led to rejection of certain studies (i.e., classified as unacceptable). This analysis included active participation by representatives of the pesticide industry (American Crop Protection Association (ACPA), formerly known as National Agricultural Chemicals Association or NACA) and the IR-4 program, the two major groups which generate residue chemistry data. For crop field trials a frequent reason for rejection was insufficient geographical representation. This could be due to either an insufficient number of trials being conducted or to the trials not being conducted in all areas of significant production for a given crop.

As a result of this analysis, the document entitled ''NACA Recommendations for Residue Site Selection and Number of Field Trials'' (hereafter referred to as the ''ACPA proposal'', see paragraph (l)(9) of this guideline) was prepared by members of ACPA, USDA and IR-4 and submitted to EPA in September 1992.

(ii) **Summary of ACPA proposal.**

ACPA /IR-4/USDA proposed dividing crops into 3 groups (based on total acres) for purposes of defining the number and location of crop field trials:

Major crops >2 million acres

Major-Minor crops >300,000 acres but <2 million acres

Minor crops ≤300,000 acres

The **number of trials** suggested for major crops (20 trials) and minor crops (3–6 trials) did not take into account factors such as dietary significance or the geographical distribution of production. Such factors were considered for the major-minor crops (8–12 trials).

With regard to **location of trials** the ACPA proposal divided the country into 13 regions based on natural geography and climatic boundaries. For distribution of trials it was stated that ''The number of trials per region should *generally* correlate with the percent of the crop grown in that area.''

(iii) **EPA analysis of ACPA proposal.**

A team of EPA senior scientists reviewed the ACPA proposal in detail and concluded it was a useful starting point. However, there were two major concerns. First, there was no consideration given to the dietary significance of the crops that ACPA had placed in the ''minor'' crop category

(3–6 trials). The Agency scientists concluded that more trials were necessary for a significant number of the fruits and vegetables categorized as minor crops. On the other hand, fewer trials were considered necessary for those minor crops with very low dietary intake. The second major concern was that the ACPA proposal did not address the definition of a site, how samples should be collected, and the number of samples per site. The proposal was revised to take into account the above concerns.

Crop field trial topics such as definitions of site, numbers of trials, sampling, and distribution of trials are discussed in more detail below. Tables are also included to specify the numbers of trials for many crops, crop groups, and crop subgroups; the percentages of crop production by region; and suggested distribution of trials in each region for numerous crops.

(iv) **Sampling requirements.**

With respect to how samples should be collected, the Agency will continue to base tolerances on *composite* samples. As to the number or weight of agricultural commodity that should be collected for each composite sample, petitioners should follow the Codex ‘‘Guidelines on Minimum Sample Sizes for Agricultural Commodities from Supervised Field Trials for Residue Analysis’’, ALINORM 87/24A (1987)(see Attachment 8 of Appendix A of this guideline). In each field trial report the petitioner should indicate whether or not these guidelines were followed. If they were not, an explanation should be provided along with details on how the sampling deviated from the Codex recommendations. Petitioners should also include in the field trial report the number of agricultural commodity units making a composite as well as the weight of the composite sample.

With regard to the **number of samples** per site, the Agency has decided that more than one treated sample is needed to provide some estimate of variability, but that three or more samples are unlikely to result in much additional information since compositing will tend to mask much of the variability. Therefore, the Agency has concluded that two independently composited samples should be collected at each site (i.e., for each field trial--with the exception of crops needing only 1–2 trials as described later in this section). The treated samples may be taken from two separate plots or from the same plot. In addition, at least one control (untreated) sample should be collected and analyzed at each site.

In those cases where the two treated samples are obtained from the same plot, it needs to be emphasized that the samples be collected by two separate runs through the plot following the aforementioned Codex guidelines. Splitting one sample from a plot or conducting two analyses on one sample will not be an acceptable alternative to separately collecting and analyzing two samples. In other words, *multiple analyses of a single sample or of subsamples constitute the equivalent of only one data point.* (However,

as explained below, if such multiple analyses are conducted, each value should be reported and clearly indicated as to which sample it represents.)

For crops which require only 1 or 2 field trials (≤200 and >200–2000 acres, respectively), at least one composite sample should be collected from each of the four separate treated plots (plus the control plot) at each site. It is strongly suggested that more than one sample be collected from each plot. Two plots should be treated at the proposed or registered application rate (1x) and two plots at a 2x rate. Furthermore, each plot should receive independently prepared applications of the pesticide. In other words, the same tank mixture should not be used to treat more than one plot. This will allow some assessment of variability due to factors such as preparation of the tank mix. [NOTE: As discussed in the next section of this document, petitioners always have the option of conducting three or more field trials at the 1x rate (with two treated samples per trial) instead of the one or two trials with at least four treated samples per trial and plots reflecting both 1x and 2x rates.]

With regard to the handling of samples at the residue analysis stage, petitioners should follow the guidance in Section 142 of FDA's Pesticide Analytical Manual, Volume I (PAM I) on sample compositing and comminuting. Multiple analyses of a sample are not required, but are advised as a check in those cases where the residue values from the two composite samples are significantly different.

In all field trial reports petitioners need to indicate clearly whether each reported residue refers to a separate sample or a second analysis of the same sample. In either case, all analyses should be reported-petitioners should not average multiple analyses of a single sample or the results of multiple samples in a trial. See also OPPTS guideline 860.1000 for a discussion of submission of raw data concerning this point.

(v) **Number of trials for individual crops.**

The required number of trials for a crop can be found in either Table 1 or Attachment 7 (column ''REQ FT'') (see Appendix A of this guideline). Table 1 is an alphabetical list of crops with the minimum number of trials and treated samples. Attachment 7 lists the crops in order of number of required field trials, but does not specify numbers of samples. However, Attachment 7 does include the acreages and consumptions of crops that were used to determine the number of trials as discussed below. Although the list of crops is not all inclusive, an attempt was made to include all crops for which acreage and/or consumption information was available. With regard to names for crops, the Index to Commodities as published in the proposed ''Pesticide Tolerances; Revision of Crop Groups'' rule (see paragraph (l)(10)) was used.

The Agency believed that dietary significance needed to be a greater factor than in the ACPA proposal for determining the amount of residue data required for each crop. First, criteria were developed to assign a base number of field trials dependent solely on total U.S. acreage of the crop. Acreage was used instead of production by weight since the former is more consistent from year to year. The primary sources used for acreage information were USDA's *Agricultural Statistics* (see paragraph (l)(11)) and the *Census of Agriculture* (Department of Commerce, see paragraph (l)(12)). IR-4 also provided information on some low acreage crops that are not included in the aforementioned publications. When acreage figures varied between sources, the highest figure was used. Acreage from Puerto Rico was included for coffee and bananas since such production was greater than or comparable to that in the fifty states. The base numbers of field trials as a function of acreage are delineated in Attachment 7 of Appendix A. For simplicity the base numbers of trials are limited to 16, 12, 8, 5, 3, 2 and 1.

Next, criteria were developed to adjust the number of trials based on dietary importance of the commodity. The figures contained in the Agency's Dietary Risk Evaluation System (DRES) for the general population were used to make a first cut. The diets of non-nursing infants and children aged 1–6 were then examined to adjust upward the number of trials on any commodities that had significantly higher consumption by these groups than by the general population. The consumption percentages used are those of the whole diet (i.e., food plus water consumption) and are shown along with the acreages of crops in Attachment 7.

For crops having 8–16 base trials (>300,000 acres), it was decided that the number of trials could be increased or decreased based on human consumption. Crops which comprise >0.4% of the general population diet had the number of trials increased by one level (e.g., 8-12, 128-16). For those crops having 16 base trials, the number of trials was increased to 20 if they comprise >0.4% of the diet. In addition, any crop with >300,000 acres and comprising >1.0% of general population consumption requires at least 16 field trials. This particular criterion results in an increased number of trials for apples, oranges, and tomatoes. On the other hand, crops with >300,000 acres accounting for <0.1% of consumption had their number of trials decreased by one level. The crops affected by this criterion are primarily or exclusively animal feeds: alfalfa, clover, cotton, grasses, and sorghum.

For crops ≤300,000 acres the Agency has concluded that due to the small number of base trials (≤5) for such crops, it would not be appropriate to decrease the number of trials based on low consumption. However, any such crops comprising ≥0.02% of the general population diet had their number of trials increased by one level (e.g., 38-5, 58-8). This criterion

affected a significant number of fruits and vegetables such as broccoli, carrots, grapefruit, lettuce, peaches, pears, and snap beans.

Addressing concerns raised in the recent National Academy of Sciences (NAS) report entitled‘‘Pesticides in the Diets of Infants and Children (see paragraph (l)(13)), the Agency also looked at the contribution of crops to the diets of **non-nursing infants and children** 1–6 years of age. In most cases, crops that are significant in these diets are also important in the diet of the general population. However, **rice** and **oats** were found to exceed the 0.4% of the diet criterion for large acreage crops using the infant diet, but not when using the diet of the general population. Therefore, the number of trials for these two crops was increased from 12 to 16. In addition, **peaches** comprise a much higher percentage (1.12%) of the non-nursing infant diet than of the general population diet (0.366%). Therefore, the number of trials required for peaches was increased from 8 (number based on general population) to 12. [Based on the relatively low acreage of peaches, it was decided not to increase the number of peach trials to 16, the number of trials required for crops having >300,000 acres and comprising >1.0% of the diet.]

For a number of crops no information could be located as to total acreage. The acreage for such crops is ‘‘0.00’’ in Attachment 7 of Appendix A. While most of these are almost certainly very minor crops, for such crops a minimum of three field trials will be required unless documentation of national acreage can be provided to show fewer trials are an acceptable number.

In addition to total acreage and percentage of the diet, one other factor was considered in determining the number of trials for crops. The Agency believes that the number of trials can be reduced if most of a crop is grown in one region. Therefore, for most crops which have ≥90% of their production in one region the number of trials has been reduced one level (e.g., 88-5, 58-3). Crops subject to this reduction include avocadoes, olives, and pistachios. It should be noted, however, that for some crops having >90% of production in one region the number of trials was not reduced due to the dietary significance of these commodities. In the case of crops which only require 3 trials based on total acreage but have ≥90% of production in one region, registrants/petitioners will have the option of conducting 3 trials with 2 treated samples per trial *or* 2 trials with 4 treated samples each (4 plots per trial--two at 1x rate and two at 2x rate as described above). Some of the crops having this option include globe artichokes, brussels sprouts, figs, mangoes and parsley. For crops which require ≤2 trials based on total acreage, there will be no reduction based on production being primarily in one region.

The effect of the 90% production being in one region can be ascertained by comparing the ‘‘REQ #FT W/O 90%’’ AND ‘‘REQ #FT’’ columns

in Attachment 7. Those crops which have a smaller number of trials in the ‘‘REQ #FT’’ have received a reduction due to ≥90% of production being in one region. The ‘‘REQ #FT’’ column agrees with the ‘‘Minimum No. of Trials’’ column in Table 1 of Appendix A.

For the purposes of standardizing the number of required field trials, it should be emphasized that in most cases (see next paragraph) the number of trials based on the above criteria and listed in Table 1 of Attachment 7 (REQ #FT) represent the *minimum* number of trials that will be accepted (with the exception of crop group tolerances or uses resulting in no quantifiable residues as described later in this guideline). Additional trials are always welcome and, in fact, encouraged in the sense that more data points provide greater certainty of expected residue levels.

As discussed above, EPA has taken into consideration several major factors to determine the necessary numbers of trials and believes these numbers will be applicable in most cases. However, in limited circumstances the Agency may require additional trials or accept fewer trials than specified in Table 1. Any registrant/petitioner believing that fewer trials are adequate for a given crop will need to provide a convincing rationale. In such cases the Agency strongly advises registrants/petitioners to submit a protocol (outlining number and locations of trials) and rationale *before* initiating such trials. Likewise, any residue chemistry reviews requesting additional trials will include a justification as to the need for such data.

The numbers of trials in Table 1 or Attachment 7 represent how many *acceptable* trials are required reflecting the label use pattern producing the highest residue. In most cases such trials include the maximum rate per application and per season, the minimum intervals between applications, and the minimum preharvest interval. Trials which reflect other use patterns will not be counted unless the difference in use is insignificant (e.g., application rate 5% higher; PHI of 23 days versus 21 days). In those cases where multiple use patterns are desired and it is not clear which would result in the highest residue (e.g., different PHI’s as a function of application rate), the full number of trials will be needed for each use unless side-by-side studies consistently show higher residues from one use pattern. [Additional guidance on this subject for early season uses appears in a later section of this guideline.] Registrants/petitioners should also be aware that trials which for some other reason do not generate viable samples reflecting the proposed use will not be counted. Possible causes of the absence of such samples are crop failure, mislabelling of samples, contamination, and insufficient documentation of sample integrity from collection to analysis. For these reasons it would be prudent for petitioners to conduct at least the field portions of a greater number of trials than the minimum listed in Table 1.

The Agency believes that one or two trials are adequate for very low acreage crops (≤200 and >200-≤2000 acres, respectively). A greater uncertainty in residue levels is tolerable for these crops based on their extremely low contribution to the diet. However, if considerable variability is encountered between plots or between trials for such crops, the Agency may set the tolerance noticeably higher than the highest observed residue. In such scenarios registrants/petitioners have the option of conducting additional field trials to attempt to show that a lower tolerance level would suffice. In fact, registrants/petitioners always have the option of conducting three or more field trials at the 1x rate (with two treated samples per trial) instead of the one or two trials with at least four treated samples per trial and plots reflecting both 1x and 2x rates.

Additional points need to be made with regard to the numbers of trials listed in Table 1 or Attachment 7:

1. Residue decline studies are included for many uses on crops needing ≥5 trials. Refer to the next section of this guideline for details.

2. These numbers are based upon each crop being the only one within its crop group for which a tolerance is requested. Refer to the *Crop Group Tolerances* section for how many trials are needed for uses on crop groups.

3. Fewer trials may be accepted for uses that do not yield quantifiable residues. Refer to the appropriate section later in this guideline for details.

4. The numbers are also predicated upon only one formulation type being requested for use on each crop. Refer to the *Formulations* section for data requirements for additional types of formulations.

5. The spray volumes specified for certain uses, especially ultra-low volume (ULV) and orchard uses, can affect the number of required trials. This is discussed in more detail later in this guideline.

6. Fewer trials will be needed for an amended registration provided the existing tolerance is shown to be adequate. Refer to the appropriate section later in this guideline for more details.

7. Table 1 addresses only **national registration** of terrestrial uses on **domestic** crops. Import tolerances are not covered. Refer to Attachment 11 of Appendix A for guidance on crop field trials to support regional and 24(c) registrations.

8. The numbers represent trials required for **permanent** tolerances. With the exception of the small acreage crops, fewer trials will normally be accepted for temporary tolerances (experimental use permits).

9. Validated analytical methodology, appropriate storage stability data, and documentation on sample handling, shipping, and storage intervals and conditions from sampling to analysis are needed to support all field trials.

10. Sampling and analysis of **treated and control samples for each raw agricultural commodity** of a crop as specified in Table I of OPPTS guidelines 860.1000 (e.g., corn grain, forage and fodder) should be included in all field trials unless a practical livestock feeding restriction is placed on the pesticide label for a commodity. One exception to this is cotton gin byproducts, for which six trials (three each for ''stripper cotton'' and ''picker cotton'') are required as opposed to twelve trials being needed for cottonseed.

11. Commercially important **varieties** of a crop as well as **seasonal variations** (e.g., winter wheat vs. spring wheat) should be covered by the field trials. Data on different varieties are especially important if there are significant differences in size and/or length of growing season. Residue data from **more than one year** are desirable, but not required for national registration. [NOTE: Data from more than one year will be required for regional registration of crops which require ≥8 trials for national registration as detailed in Attachment 11.]

12. The numbers of trials are intended to cover terrestrial food uses on growing crops. They do not address **postharvest** applications to commodities such as fruit or stored grain. These will continue to be handled on a case-by-case basis.

13. Unless radiolabeled data show a seed treatment to be a non-food use, it will not be treated differently than any other food use. However, in many cases such uses may be eligible for the 25% reduction in the number of trials due to residues being below the method's LOQ.

(vi) **Residue decline studies.**

Residue decline studies are required. Such data will be needed for uses where (1) the pesticide is applied when the edible portion of the crop has formed *or* (2) it is clear that quantifiable residues may occur on the food or feed commodities at, or close to, the earliest harvest time. The primary purpose of these studies is to determine if residues are higher at *longer* preharvest intervals than requested and the approximate half-life of the residues. In addition, such studies are frequently of great value for determining an appropriate tolerance when a use pattern is changed. The number of decline studies needed is one for crops requiring 5–12 total trials and two for crops requiring 16–20 total trials. These studies are included in the 5–12 or 16–20 trials (i.e., not ''in addition to'' these

numbers of trials). Decline studies will not be required for crops needing ≤3 total trials.

The design of the decline studies should include 3-5 sampling times in addition to the requested preharvest interval (PHI). The sampling times should all fall within the crop stage when harvesting could reasonably be expected to occur. The time points should be approximately equally spaced and, where possible, represent both shorter and longer PHIs than that requested. Of course, shorter PHIs can not be examined in the case of a use with a zero day PHI. In addition, for an at-plant/pre-plant use, the PHI is usually predetermined by the length of the growing season of the crop. Therefore, for such uses that result in quantifiable residues, petitioners should attempt to stretch the harvest period by sampling immature fruit, tubers, etc. if necessary.

Only one composite sample will be required for each time point in a decline study. However, petitioners are advised to take two or more samples to prevent method and sampling variability from masking or appearing to create residue changes with time.

For most pesticides it is anticipated that residue decline studies will not be necessary for all crops. For a given pesticide additional decline studies will not be required if studies on representative crops indicate residues do not increase with longer preharvest intervals. This will provide some assurance that the tolerances represent the maximum residues that will occur from proposed or registered uses of a pesticide. The representative crop approach to be used is similar to that described in OPPTS guideline 860.1380. If a pesticide is to be applied to all types of crops, it is recommended that decline data be obtained on the following five representative commodities: a tree fruit, root crop, leafy vegetable, grain, and fruiting vegetable. Some flexibility in the choice of crops will be permitted. For example, a legume vegetable could be substituted for the fruiting vegetable.

(vii) **Crop group tolerances.**

As mentioned above, the numbers of trials in Table 1 are based upon each crop being the only one within its crop group for which a tolerance is requested. In the case of **crop group tolerances** for which there is more than one representative crop, the number of trials can be reduced based on the reasonable assumption that residues in the representative commodities should reflect residues on all crops in the group. The reduction in the number of trials is 25% (i.e., 20-15, 16-12, 12-9, 8-6) for those representative commodities that need ≥8 trials when requested individually. Crops which require ≤5 field trials will not receive any reduction when used as a representative commodity. Table 2 of Appendix A shows the resulting numbers of trials needed for all crop groups in 40 CFR 180.41.

As stated in 180.41, if maximum residues for the representative crops vary by more than a factor of 5 from the maximum value observed for any crop in the group, a group tolerance will ordinarily not be established. In this case individual crop tolerances will normally be established and the 25% reduction in the number of trials will *not* apply. Petitioners should keep this in mind when planning crop field trials for crop group tolerances.

It should be noted that a similar 25% reduction in the number of trials may be applied to uses that do not yield quantifiable residues (see next section of this guideline). However, both of these 25% reductions may *not* be applied to the same crop. In other words, the number of trials can not be reduced 50% for a representative commodity that does not contain quantifiable residues.

The Agency has recently finalized the creation of **subgroups** within the existing crop grouping scheme (‘‘Pesticide Tolerances; Revision of Crop Groups’’, Federal Register Vol. 60, No. 95, pp. 26625–26643, 5/17/95) (see paragraph (l)(10)), guidance on the number of field trials needed for the representative commodities in these subgroups is also provided in Table 3 of Appendix A. These numbers of trials were determined on a case-by-case basis looking at the acreages and consumption of the representative commodities and the whole subgroup. Refer to the footnotes of Table 3 for more details.

In effect, some crop groups have been established in 40 CFR 180.1(h). For example, a tolerance on ‘‘onions’’ applies to ‘‘dry bulb onions, green onions, and garlic’’. To determine the number of trials required for the ‘‘groups’’ in 180.1(h), refer to Table 4.

Although there is no crop group for ‘‘small grains’’ in CFR 180.41, for data generation purposes wheat, barley, oats, and rye may be treated as a group. Provided use patterns and resulting residues are similar, the numbers of trials for wheat, barley, and oats may be reduced to 15, 9, and 12, respectively. Five trials are still needed for rye. The tolerances will be established on the individual crops due to the lack of an official small grain crop group.

(viii) Uses resulting in no quantifiable residues.

Provided metabolism data or field trial data on related crops indicate quantifiable residues are not likely, a petitioner may elect to conduct 25% fewer trials for crops normally requiring ≥8 trials. However, if all of these trials do not show **residues below the method’s limit of quantitation** (LOQ), additional trials will normally be required to bring the total number conducted up to the standard requirement. Thus, the registrant/ petitioner could risk a delay in obtaining a tolerance if this option is chosen. In addition to residues being below the LOQ, two other conditions must be met for

the 25% fewer trials to be acceptable. First, the method must have a sufficiently low LOQ both from an analytical chemistry standpoint and for risk assessment purposes. This means the LOQ will need to be in the ≤0.01–0.05 ppm range in most cases. Second, the trials still need to represent all significant regions of production. Distribution of trials across regions is discussed in more detail in a later section of this guideline.

As explained earlier in this guideline, the 25% reduction in the number of field trials for residues below the LOQ can *not* be applied to representative commodities being used to establish crop group tolerances. The reduction is also not applicable to crops that require ≤5 field trials.

For crops which have more than one raw agricultural commodity, the 25% reduction for residues below the LOQ may be applied to one commodity even if the others have quantifiable residues. For example, if a pesticide is applied to an early stage of corn, it is possible residues are found on forage and fodder, but not in the grain. In this case, 16 trials may be acceptable for grain, even though 20 are needed for the forage and fodder. This is not meant to imply that separate trials are to be conducted for different crop parts. In other words, corn grain, forage and fodder should be collected from each trial site. If no residues are found on grain from a minimum of 16 geographically representative sites, the grain collected at other sites need not be analyzed.

To take advantage of this option, registrants/petitioners should be certain to submit adequate recovery data and chromatograms establishing the limit of quantitation of the method. If the method ends up being validated in Agency laboratories, the LOQ will be included in the fortification levels that are tested. For a definition of LOQ the Agency suggests the article ‘‘Principles of Environmental Analysis’’, *Analytical Chemistry*, **1983**, 55, 2210-2218 (L.H. Keith, et al).

(ix) **Additional considerations for early season uses on annual crops**.

For pesticide applications made prior to crop emergence, many labels give options such as allowing the use to be pre-plant, at-plant, or pre-emergence. The Agency has concluded that these three types of application can be grouped for the purposes of determining the total number of field trials. In other words, the trials for a specific crop can be divided among these three applications at the registrant/petitioner’s discretion. For example, the twelve trials for a particular pesticide on cotton could consist of 3 pre-plant, 3 at-plant, and 6 pre- emergence applications (plus the maximum rate and number of any proposed post- emergence applications--see last paragraph of this section).

If the label gives a choice for surface application versus incorporation into the soil, data reflecting both of these modes of application will be required. There are two options as to how to conduct and determine the number

of trials in this instance. The preferred option is for each trial to include both the surface and incorporated applications on side-by-side plots. Only one composite treated sample would be required for each plot. The minimum number of trials should be as designated in Table 1. This means that the total number of samples would be equivalent to that required for most other uses on the same crop. Using cotton again as the example, at least twelve trials would be needed with each having two samples (one for surface applied and one for soil incorporated). As described in the previous paragraph, the 12 trials can be divided among pre-plant, at-plant and pre-emergence applications if all these appear on the label.

The alternative option is to divide the total number of trials in Table 1 (*but* note caveat below) roughly equally between those having only the surface treatment and those reflecting only soil incorporation. Two composite treated samples will be needed in each trial. Since the trials for each mode of application will need to have adequate geographic representation, this option may result in a greater number of trials for those crops which have a region(s) normally needing only one trial. Using the cotton example, the result would be at least two additional trials (14 total) since regions 6 and 2 (representing 10% and 8% of production, respectively) would each need to have two trials (one for surface and one for incorporation). If the side-by-side option above were chosen, only one trial would be required in each of those regions.

Particularly in the case of herbicides, the label may permit pre-and/or post-emergence applications. If both are allowed, *all* field trials should include both applications. If the choice is limited to one *or* the other, the full number of trials as specified in Table 1 should be conducted for *each* type of application. However, fewer total trials will be accepted if some side-by-side studies show a consistent pattern between the residues from the pre- and post-emergence uses. In this instance the full number of trials will be needed only for the mode of application consistently resulting in higher residues. [NOTE: The discussion in this paragraph refers to before or after the emergence of the food/feed *crop.* Occasionally, labels specify application timing in terms of before or after *weeds* emerge. The critical factor for purposes of this discussion is whether or not the food/feed crop has emerged.]

(x) **Formulations**.

In the ‘‘Number of Trials for Individual Crops’’ section of this guideline it is stated that the numbers are based upon only one formulation type being requested for use on each crop. The number of trials needed to register additional formulation types or classes will be addressed on a case-by-case basis. In some instances the full number of trials will also be needed for a new type of formulation, whereas other formulation classes may be registered with a few bridging studies or perhaps no field trials at all. The decision depends upon how similar the formulations are in composi-

tion and physical form, the mode of application, and the timing of the application. More details are provided below.

One type of formulation which will normally require a full set of field trials is the microencapsulated or controlled release formulation. Since these are designed to control the release rate of the active ingredient, the same number of field trials is needed as to obtain an original tolerance regardless of the timing and mode of its application and the amount of data available on other formulations classes.

Most of the remaining types of formulations can be divided into two groups: those which are diluted with water prior to application and those which are applied intact. Granules and dusts are the most common examples of the latter. Granular formulations will generally require the full number of field trials regardless of what data are already available for other formulation classes. This is based on several observed cases of residue uptake being quite different for granules versus other types of formulations of the same active ingredient. No residue data will be required for dusts if data are available at the same application rate and preharvest interval for a formulation applied as a wetting spray (e.g., EC, WP).

The most common formulation types which are diluted in water prior to application include emulsifiable concentrates (EC), wettable powders (WP), water dispersible granules (WDG; WG) or dry flowables (DF), flowable concentrates (FlC), and soluble concentrates (liquid or solid) (SC; SL). Residue data may be translated among these classes of formulations for applications that are made prior to crop emergence (i.e., pre-plant, at-plant, and pre-emergence applications) or just after crop emergence. Data may also be translated among these formulation classes for applications directed to the soil (as opposed to foliar treatments).

For mid-to late season foliar applications of formulation types listed in the previous paragraph, two options are available. The new type of formulation could be treated similarly to an amended registration (see later section): 25% fewer trials would be required than were required for the formulation class used to obtain the original tolerance. Alternatively, side-by-side studies (often referred to as bridging data) could be conducted. These involve applications of the registered formulation (the type used to obtain the tolerance) and the new type of formulation to side-by-side plots using the same rates and pre-harvest intervals. If residues from the new formulation are comparable to or less than those from the registered formulation, the new formulation can be registered. However, if residues are higher from the new formulation in the side-by- side comparison, the full number of trials specified in Table 1 will be required for that formulation to determine the higher tolerance level needed to cover its registration.

The exact number of side-by-side studies required will be decided on a case-by-case basis. A ‘‘representative crops’’ approach may be used if the

new formulation is requested for use on numerous crops. Submission of protocols outlining the crops and sites to be used in these bridging studies is encouraged. The most common questions from registrants/petitioners in this area have involved use of EC data to support registrations of wettable powders. It is EPA's understanding that the American Crop Protection Association (ACPA) is compiling data from its members that compare residues from ECs and WPs. If a sufficient number of such studies are available, it is possible a conclusion could be made in the future that no additional crop field trials are required to register a WP if data for an EC reflecting the same use pattern are available.

The previous two paragraphs address the data requirements for a new type of formulation when a registered one already exists. If registrant/petitioner wishes to register two or more formulation classes when obtaining the initial tolerance and registration, the same basic concepts would apply. That is, a complete set of trials as specified in Table 1 should be conducted on one type of formulation and the additional formulation classes handled like an amended registration (25% fewer trials than the primary formulation) or compared to the primary type of formulation using side-by-side studies.

A few other statements can be made concerning data requirements for formulations. Dry flowable or water dispersible granular formulations are sufficiently similar to wettable powders to allow translation of residue data between them. Placing a formulation (typically WP) in a water soluble bag does not require additional residue data provided adequate data are available for the unbagged product.

Some pesticides (e.g., phenoxy herbicides) can be applied as one or more **salts** and/or **esters**. Generally, different salts or esters of an active ingredient can be treated as new formulations of that active ingredient for purposes of determining the number of crop field trials. Thus, a new salt could be treated like an amended registration (25% fewer trials than the original salt or form of the active ingredient) or compared to the registered form of the active ingredient using side-by-side studies.

(xi) **Spray volumes - ground versus aerial equipment**.

The subjects of spray volumes and aerial versus ground equipment are often interconnected and were addressed in PR Notice 93–2 (Feb. 11, 1993)(see paragraph (l)(15)). This notice stated the following: ''Provided that the pesticide product label specifies that aerial applications are to be made in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree or orchard crops), crop field trials reflecting aerial application will be waived in those cases where adequate data are available from use of ground equipment reflecting the same application rate, number of applications, and preharvest interval. This data waiver does not apply to aerial applications using diluents other than water (e.g., vegetable oils).

In addition, the Agency reserves the right to require aerial data if special circumstances warrant it.''

Based on the above, there are only a few instances where the number of field trials will be affected by the spray volumes or type of equipment (at least for aerial versus ground) specified on the label. However, the following two exceptions should be kept in mind:

(1) Ultra-low volume uses (<2 gallons spray per acre; <10 gallons per acre for orchards) in mid- to late season will be treated as separate use patterns regardless of the nature of the diluent (water, vegetable oil, etc.). If the ULV application is the first use on the crop (i.e., no tolerance established), the minimum number of field trials specified in Table 1 or Attachment 7 is required. If data are already available reflecting higher spray volumes, the ULV application can be handled similarly to an amended registration (i.e., 25% fewer trials than specified in Table 1 providing these trials show the existing tolerance is adequate-see *Amended Registrations* below). Alternatively, it would acceptable for registrants/ petitioners to demonstrate using side-by-side studies that residues from the ULV applications are comparable to or lower than those from higher spray volumes. However, if residues are higher from the ULV application in these side-by-side studies, the full number of trials specified in Table 1 will be required for this use.

(2) For treatment of orchards, dilute sprays (typically 100–400 gallons per acre) and concentrate sprays (typically 20–100 GPA) will be treated as separate uses. The number of trials will depend upon which of two options is chosen, analogous to the discussion earlier in this document for surface applied versus soil incorporation (see *Additional Considerations for Early Season Uses on Annual Crops).* If side-by-side plots (dilute vs. concentrate) are included at all sites (the preferred option), the numbers of trials in Table 1 will apply and one treated sample from each plot (instead of the normally required two) will be acceptable. Alternatively, the trials could be divided roughly equally between dilute and concentrate sprays with adequate geographic representation required for each type of spray. In this case, two treated samples are needed at each site and the total number of required trials may exceed that in Table 1 if one or more regions require only one study. Refer to the example for cotton in the section on Early Season Uses.

If either dilute or concentrate sprays are already approved for use on an orchard crop, the request to add the other type of spray to the label will be treated as an amended registration requiring 25% fewer trials than specified in Table 1 (see *Amended Registrations* below) or a number of side-by-side studies establishing that residues from the requested type of spray are not higher than those from the registered one. The exact number of side-by-side studies required will be determined on a case-by-case basis.

Submission of protocols outlining the locations and numbers of sites is encouraged.

One final comment on spray volumes concerns chemigation--the application of pesticides by injection into irrigation water. The Agency views this as a type of ground application using very large spray volumes. Provided that data are available for typical ground spray volumes, data reflecting chemigation are not required.

(xii) **Amended registrations**.

For amended registration requests that involve a significant change in application rate (either individual or seasonal), interval between applications, or preharvest interval, the number of field trials required will normally be 25% less than that needed to establish an original tolerance, provided that the latter is shown by the reduced number of trials to be adequate to cover the new use. However, if the reduced number of trials indicates that the original tolerance is inadequate, or if the original number of trials was ≤5 or already included a 25% reduction (crop group or residues <LOQ), the number of trials for an amended registration is the same as that for the original tolerance. On a case-by-case basis the Agency may require less additional data than described above for an amended registration. This could be particularly true when residue decline studies are available reflecting a proposed change in a preharvest interval. In some instances, no additional data may be necessary. An example would be a request to reduce the application rate for a use that already does not produce quantifiable residues.

(xiii) **Location of Trials**

The Agency divided the United States into 13 regions based on growing conditions as proposed by ACPA (see map in Attachment 9 of Appendix A). The dividing lines reflect natural geography or climatic boundaries and, therefore, in many cases do not coincide with state lines. The exact definitions of the regions are specified by states, counties, highways, or mountain ranges in Attachment 10 of Apppendix A. EPA has decided that Puerto Rico is more similar to Hawaii (Region 13) than Florida (Region 3) in terms of climate and geography. Therefore, Puerto Rico should be considered to be combined with Hawaii to form Region 13. The production figures in Table 6 and distributions of trials in Table 5 of Appendix A have been developed on this basis. Also, as noted below, it may be acceptable for trials in the southern extreme of Florida to represent Region 13.

Using crop production figures the Agency has developed suggested distributions of trials among the 13 regions for crops requiring >3 trials. These distributions are delineated in Table 5 and were developed using the following general criteria. The number of trials per region should generally correlate with the percentage of the crop grown in that region. However, where possible, at least one trial should be included in each region

having ≥2% of the national production. The latter criterion can be met in most, if not all, cases for crops requiring ≥12 trials. However, for some crops needing 5–8 trials, trying to satisfy this criterion would result in regions with a high percentage of the production having too few trials. For example, in the case of sweet cherries the Agency has not suggested that trials be conducted in Regions 1 and 9 (3% each of national production) since this would leave too few trials in the major regions of production (5, 10, 11).

The distributions of trials in Table 5 are not intended to be absolute requirements, but ''suggested'' designs for these studies. There are likely to be several acceptable alternatives for most crops. Registrants/ petitioners may wish to contact EPA regarding the suitability of alternative distributions of trials.

It should also be noted that the regional borders specified in Attachments 9 and 10 are not absolute lines; rather, they have been drawn as rough approximations of climatically similar areas. Field trials conducted within reasonable distances of regional borders can be acceptable for fulfilling requirements for the region on either side of the border as long as weather conditions and cropping practices are representative of either region. Therefore, if it can be demonstrated that a site is representative of two regions, crop field trials for both regions can be performed at that site. For example, a site in northern Florida (part of region 3) may be acceptable for a crop grown in the southern part of region 2. Similarly, the southern extreme of Florida can be regarded as bordering region 13 (Puerto Rico plus Hawaii). Field trials in southern Florida can thus be used toward satisfying the requirements for assorted tropical fruits. However, in any of these cases where a site near a border may represent two regions, the total number of crop field trials required for the two regions will *not* change. Therefore, if more than one trial is required from the two regions, sites in addition to the one near the regional border will be needed in the two regions or trials will be required for more than one year at the site near the border.

For crops requiring ≤3 trials, it is more difficult to develop guidance on distribution of trials since the number of growing regions is often comparable to or even greater than the total number of trials. In these cases the data should represent to the extent possible a balance of the highest production areas, different geographic/climatic conditions, and/or major differences in varieties of the crop. At least one trial should be conducted in the region of highest production.

To aid registrants/petitioners in determining distribution of trials for crops not listed in Table 5 or alternative distributions of trials for crops that are in that table, the production of numerous crops by region is specified in Table 6. Most of these figures were obtained using acreage information from USDA's *Agricultural Statistics* (1991) and the 1987 *Census of Agriculture* (Dept. of Commerce). These publications list production by state

instead of region. Since numerous states fall into more than one region, the distribution of acreage within these states had to be estimated to calculate regional production. Numerous crops (primarily minor crops such as spices, herbs, and unusual berries) are not listed at all in this table since no regional production figures for them were available. As can also be seen in Table 6, the total accountability of production is <100% for a considerable number of crops. However, the Agency believes sufficient percentages of production (most are >85%) are accounted for to determine the distribution of trials.

A special comment needs to be made concerning distribution of trials for crop group or (proposed) crop subgroup tolerances for legume vegetables. The regulation and new rule specify that the representative commodities include one variety of succulent bean, one variety of dried bean, one variety of dried pea, etc. depending upon the crop group or subgroup. If possible, the variety chosen should be one that is grown in all significant areas of production for that class of bean or pea. If this can not be done, then a combination of varieties may be used to encompass all regions of production. As an example, it will not be acceptable to provide data from only one region for a certain variety of dried bean even if that dried bean is grown only in that region. The data need to reflect all significant regions of production for all dried beans if a crop group or subgroup tolerance is desired.

The above discussion focuses on the distribution of trials *among* regions. With respect to the distribution of multiple trials *within* a region, this should generally follow the relative production in the individual growing areas (states or counties as appropriate) of the region. However, the sites should also be sufficiently separated to reflect the diversity of the growing region including soil types. In other words, if production is scattered throughout much of a region, the trials should not be clustered in one small portion of that region.

To aid the Agency's review process with regard to the distribution of trials among and within regions, registrants/petitioners are requested to include a copy of the map in Attachment 9 showing the locations of all sites of acceptable trials (i.e., those reflecting the proposed use and generating viable samples) in the volume of field trial reports for each crop.

(xiv) **Requirements for tolerances with geographically restricted registrations and for 24(c) registrations**.

The preceding discussion in this guideline on determining the number of crop field trials addresses national registration of pesticides. Since regional registration is accepted by the Agency under certain circumstances, separate guidance has been developed as detailed in Attachment 11 of Appendix A. This attachment also addresses field trial requirements for 24(c) or Special Local Needs registrations. In summary, the basic concept de-

scribed in Attachment 11 is that the number of trials for a regional registration should be determined by multiplying the number of field trials required for national registration by the proportion of the crop (on an acreage basis) grown in the region in which registration is sought.

(f) **Aspirated grain fractions: A tolerance perspective**.

(1) **Background**.

When cereal grains or oilseeds (e.g., corn, wheat, sorghum, barley, oats, rye, and rice, and soybeans) are moved into, transferred within, or shipped from US grain handling facilities, dust is generated as the grain moves through a transfer point, e.g., bucket elevator, one belt to another, etc.. This dust escapes as an air pollutant and is potentially damaging to workers if inhaled, and because of its flammability when it becomes airborne, it is also a highly explosive dust which creates a hazardous work environment. The Occupational Safety and Health Administration (OSHA, US Department of Labor) regulations require dust control systems in grain elevators to remove this dust both for environmental and safety reasons. The grain elevator industry has designed dust control systems to capture dust at each of these transfer points in compliance with OSHA standards. OSHA commonly refers to the elevator dust as ‘‘fugitive dust’’, and defines this dust as combustible particles ≤425 (microns μm) which escape in the handling of grain. Particles sizes <425 μm are a factor in worker inhalation, while from an explosion safety point, dust particles below 100 μm cause the major explosion hazard; even larger particles 250 to 500 μm can also be made to explode in sufficient concentrations. OSHA standards also require that grain elevators implement a housekeeping program to reduce accumulations of ‘‘fugitive dust’’ on ledges, floors, equipment, and other exposed surfaces. Thus, the elevator dust is collected by the dust control system solely to achieve worker safety and to produce good air quality at the elevator facilities, and not for grain cleaning. Of course, some cleaning of the grain is accomplished in the process. The grain elevator industry refer to this elevator dust as ‘‘**grain dust**’’. However, the livestock feed manufacturers for aesthetical reasons commonly refer to this material as ‘‘**aspirated grain fractions**’’. Since the Agency interest is related to livestock feeding ‘‘**aspirated grain fractions**’’ is the preferred term in this discussion of elevator ‘‘**grain dust**’’.

Dust captured by above systems is divided into three types: l) dust removed from the grain stream and collected into dust bins, 2) dust sweepings gathered from the elevator floors, equipment and other elevator areas, and 3) dust removed from grain stream by a dust recirculation/recombination (R/R) system. Many facilities disposed of this aspirated dust either by recombining with the grain as it is moved through the elevators, or by dumping into landfills or the waterways, or by processing into animal feeds. Since many landfills or waterways will no longer accept aspirated dust, other disposal methods have been investigated, i.e., burning

at elevator sites to provide heat energy, using in building materials and roadways, etc., but not with great success. Thus disposal via animal feeds may become more important since it is a nutritious livestock feed somewhat comparable to the whole grain, and therefore an acceptable disposal method.

Changes in the grain standards by the Grain Quality Improvement Act of 1986 (GQIA)(see paragraph (l)(16)) prohibit the recombination or addition of previously collected ''**aspirated grain fractions**'' once it has been removed at the **export** facilities and have consequently increased the volume of ''**aspirated grain fractions**'' available for disposal. This includes all three types of dust that are generated at elevators: bin dust, dust sweepings, and recirculation/ recombination dust. The Federal Grain Inspection Service (FGIS), after public comments on the GQIA, adopted the final rules (Federal Register, Vol. 52, No. 125, June 30, 1987, pp. 24414–24441)(see paragraph (l)(17) that prohibit the addition of dust from bins and sweepings to grain at export facilities. However, based on public comments, FGIS has not yet implemented the prohibition of recombining recirculation (R/R) dust to the grain stream, and has deleted this proposal from the final rule-making until additional data are gathered for the recirculation/recombination dust. In addition, although not prohibited by law, FGIS has recommended that operators of non-export elevators (i.e., country and inland terminals) refrain from the recombination or addition practices of bin dust and dust sweepings, but not including the R/R dust. If the addition of R/R dust back into grain is also prohibited, then the volume of dust that must be disposed will increase, and more dust will possibly be available for use in animal feeds.

Since various pesticides are applied either preharvest to growing grains or postharvest to stored grains, the harvested/stored grains could have pesticide surface residues which could concentrate in the aspirated dust. This concentration occurs from postharvest treatment because pesticide residues are absorbed onto the large surface areas of the dust particles on the grain. The particle sizes of the dust can range from <1 μ m to 2500 μm, with as much as 50% being <100 μm. Incorporation of this fine dust into animal feeds can cause increased exposure of pesticide residues to animals, and these residues could be transferred into the human food chain through livestock meat, milk, or eggs. Concentration of residues in aspirated dust can also potentially occur if measurable surface residues of pesticides are found on harvested grain/oilseeds even from preharvest treatment.

The incorporation of ''**aspirated grain fractions**'' into animal feeds would fall under the auspices of the Federal Food, Drugs, and Cosmetic Act (Amended January 1980) if a tolerance for pesticide residues is needed as a result of moving cereal grains and oil seeds through commerce.

(2) **Definitions/characteristics.**

The 1993 Official Publication of the Association of American Feed Control Officials (AAFCO)(see paragraph (l)(18)) defines ‘‘**grain dust**’’ (Section 60.43) as ‘‘**aspirated grain fractions**’’. [(IFN 4–12–208) Cereals-oil seeds grain and seed fractions aspirated.]: ‘‘**Aspirated grain fractions**’’ are obtained during the normal aspiration of cereal grains and/or oil seeds for the purpose of environmental control and safety within a grain handling facility. It shall consist primarily of seed parts and may not contain more than 15% ash. It shall not contain aspirations from medicated feeds.’’ (Note: Medicated feeds refer to those treated with animal drugs; Ash is defined as the mineral residue remaining after combustion in air.). [International Feed Numbers and Names (IFN) were developed and provided by the Feed Composition Data Bank, USDA National Agricultural Library, Beltsville, MD.].

A related grain byproduct is called ‘‘**chaff and/or dust**’’. This material is collected in grain processing plants solely to clean the grain, whereas ‘‘**aspirated grain fractions**’’ are collected at grain elevators for environmental and safety reasons. The AAFCO defines ‘‘**chaff and/or dust**’’ [IFN 4–02–149 Cereals-legumes chaff and/or dust (Section 81.3, Screenings)] as follows: ‘‘**Chaff and/or dust**’’ is material that is separated from grains or seeds in the usual commercial cleaning processes. It may include hulls, joints, straw, mill or elevator dust, sweepings, sand, dirt, grains, seeds. It must be labelled, ‘‘chaff and/or dust’’. If it contains more than 15% ash the words ‘sand’ and ‘dirt’ must appear on the label.’’ ‘‘**Chaff and/or dust**’’ is normally recombined with unprocessed broken grain pieces and/or bran before being used in animal feeds. Any pesticide residues in regard to tolerance needs would be considered in grain byproducts from the grain processing.

Therefore, only the residue data requirements of the tolerance setting process for ‘‘**aspirated grain fractions**’’ need to be considered in this guideline.

Although ‘‘**aspirated grain fractions**’’ can be defined in general by IFN 4–12–208, more specific characteristics for this dust are not as easily defined. First, the dust collection systems are designed to achieve safety and air quality, and not to isolate the dust by particle size or content, i.e., dust, and/or chaff, bran, other light materials. There are no specific guidelines or industrial standards of dust collection equipment for grain handling facilities. Second, the large variability of the dust composition is governed by the location, time of year, and crop condition at harvest, as most elevators handle grains on a seasonal basis, e.g., wheat in the summer, and corn, sorghum, and soybeans in early fall. Third, the dust is not normally segregated by an individual grain or seed commodity as it is collected, but is trapped in a common container or bin. Normally this dust will be recombined with other transient grain at the elevator site. Thus, a composite of this aspirated dust will probably be found at inland and export

terminal elevators. In general, aspirated dust from one commodity will only be found at country elevators.

(3) **Utilization in animal feedstuffs.**

Based upon the feed industry uses of ‘‘**aspirated grain fractions**’’, the estimate of 20% of the diet is to be used for all livestock, although some research has shown that the dust can be fed up to 50% to cattle and swine. ‘‘**Aspirated grain fractions**’’ is normally mixed with other feedstuffs (e.g., molasses as a binding agent), or it can be pelleted by mixing with alfalfa meal at 50% to produce ‘‘range cubes’’ which are fed possibly at 20–30% in addition to other feedstuffs, e.g., grasses, hay, etc. Dairy farmers and processors of dairy feeds also tend not to use ‘‘**aspirated grain fractions**’’ in feeds because of the possibility of pesticide contamination of milk. Leading US poultry producers have stated that the current poultry production practices prevent the use of ‘‘**aspirated grain fractions**’’ in their feed mixes because of the possible presence of high pesticide concentrations in the feed which can result in a lower weight gain for broiler and/or a drop in egg production with laying hens. Thus, the inclusion of ‘‘**aspirated grain fractions**’’ in poultry diets should not be considered. It also appears that much more of the dust may be used for beef cattle, than for other livestock.

Based upon the US export volumes it appears that corn, wheat, sorghum, and soybeans are the major grains/oil seed that will generate significant volumes of elevator dust. Barley, oats, and rye would make up a very small percentage (<2%) of the total ‘‘**aspirated grain fractions**’’ available for animal feeds. In addition, rice grain dust is not used in animal feeds because of a high silica content of >30%.

Because of different growing patterns, i.e., difference in the grain exposure because of protective glumes around the kernels in several crops, and possibly different application patterns of the pesticide, individual data will be required for corn, wheat, sorghum, and soybeans, and should not be translated from one to the other to support a proposed or registered use.

Presently the grains of corn, wheat, and sorghum, and the seed of soybeans are considered rac’s. When the grain is harvested and stored some dust is present on the grain. ‘‘**Aspirated grain fractions**’’ from these crops are removed by aspiration methods for environmental and safety reasons as the grain and seed are moved through commerce. This dust is normally added back to the whole grain/seed as it travels through country and inland elevators, with final removal, in many cases, occurring at the export elevators. Removal and/or addition of this aspirated dust does not change the rac. There is no processing **per se** involved in its removal or its addition. Therefore, for consistency, ‘‘**aspirated grain fractions**’’, which is only a portion of the whole grain or seed at harvest and storage, should also be considered a rac.

According to the grain elevator industry, ‘‘**aspirated grain fractions**’’ is normally a composite of more than one grain. The collected dust from the grain being moved through the elevator is added to a common dust bin, meaning that the dust from corn can be added to dust from wheat, the dust from sorghum can be added to corn, etc. Therefore, a tolerance for ‘‘**aspirated grain fractions**’’ should be established for the pesticide, and this tolerance should consider the use of a pesticide on corn, wheat, sorghum, and/or soybeans. For example, if the pesticide is used only on one grain/oil seed, then the tolerance should be established assuming this crop will represent 100% of the dust. If the pesticide is used on several crops, then the rac with the highest residues in the dust will be used to establish the tolerance.

(g) **Test method.**

Presently residue data for ‘‘**aspirated grain fractions**’’ are required for all postharvest applications of pesticides for corn, wheat, sorghum, soybeans, and on some preharvest applications for these crops with a zero day or short PHI whose seed heads are formed at the time of application.

Residue data should be submitted in support of all postharvest uses. Data needs for a **preharvest** use follow the discussions on postharvest uses.

For a **postharvest** use the following can be used as a reference to help design a laboratory experiment to measure residue levels in ‘‘**aspirated grain fractions**’’ from transient grains in elevator operations. Only one residue study is needed for each grain (corn, wheat, sorghum, soybeans) that is treated post-harvest (or has a pre-harvest use resulting in quantifiable residues as described below).

If the pesticide is currently registered for a postharvest use, then treated grain from a commercial operation can be used. The treated grain should be analyzed for residues of the pesticide under investigation, then cleaned by an aspirated method identical or similar to a commercial elevator operation to trap the dust. For each 100lb of grain, the amount of dust should be approximately 200 g. Depending upon thepesticide residue levels, this may or may not be a sufficient amount for fractionation and analyses; larger quantities of grain may be utilized. Next, the cleaned grain andthe dust should be analyzed for the pesticide residues, and the level of pesticide residue concentration determined. However, before analysis of the dust, it should befractionated into 4 or 5 different ranges, e.g, under 400 μm, 400 to 800 μm, 800 to 1200 μm, 1200 to 2000 μm, and 2000 to 2500 μm, or any other similar sieve sizes to determine the particle size distribution. The purpose of this distribution data is to show that the aspirated dust sample typifies a sample of commercial elevator ‘‘**aspirated grain fractions**’’; normally, at least 50% of the elevator ‘‘**aspirated**

grainfractions'' have a particle size of <400 μm. But, for purposes of residue analysis, the pesticide treated dust should be recombined since this reconstituted dust sample would be more representative of ''aspirated grain fractions'' used in commercial feed production and/or feeding practices. In addition, since ''**grain fractions**'' are defined according to the American Feed Control Association to contain ash at less than 15%, the ash content of the combined dust fractions should also be determined. The elevator dust sample should be analyzed using methodology for the pesticide under investigation which does not exhibit interference problems from residues of other registered cereal/oilseed pesticides that might be present from prior applications. It is recommended that triplicate samples be taken. Duplicate analyses of pesticideresidue levels should be performed on all samples.

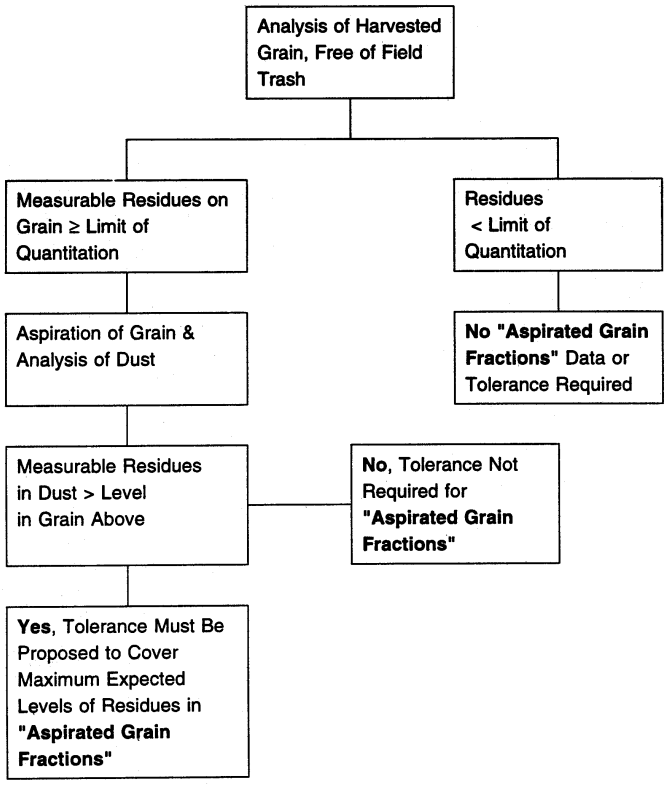
An alternative procedure for either a currently registered postharvest pesticide, or aproposed registration of a newly developed postharvest pesticide could be as follows.

First, ''**aspirated grain fractions**'' that has been collected by a commercial elevatoraspiration system should be acquired. A particle size distribution of the aspirated dustshould be measured from 2500 (or 2000) μm to under 400 μm (using 4 or 5 sieve sizes to cover this range as described above), and the ash content determined. Analysis of the untreated dust sample as the control will indicate any problems if other pesticides are present from prior applications. A sample of the grain should becleaned by aspiration, using a method identical or similar to commercial operations. Next, using the unfractionated aspirated dust sample that was aquired as described above from a commercial grain elevator, apply the dust to the cleaned grain at a rate of 0.2% (by weight), and mix to distribute the dust evenly over the grain. Apply the pesticide at its maximum allowable label rate, and after the solvent has dried, aportion of the grain, which is now covered with the aspirated dust and the pesticide, should be sampled for analysis. Remove the treated dust from the grain by an aspirated method, and analyze this cleaned grain and the treated dust for pesticide residues. It is recommended that triplicate samples be taken. Duplicate analyses of pesticide residue levels should also be performed on all samples. The level ofconcentration should be determined for the pesticide using average results. The tolerance level for the aspirated grain fractions is then calculated using thisconcentration factor and the tolerance for the grain.

Storage stability data on the whole grain will adequately support storage of ''**aspirated grain fractions**'' samples prior to residue analysis. Refer to OPPTS guideline 860.1380 for guidance on generating storage stability data.

One application at the maximum allowable label rate, followed by the collection andthe analysis of the ‘‘**aspirated grain fractions**’’ for the pesticide immediately after application, should provide sufficient data to adequately determine the expected level of a pesticide in commercial elevator ‘‘**aspirated grain fractions**’’. The collection and analysis of this dust should follow the above suggestions for the gathering of ‘‘**aspirated grain fractions**’’ data from a postharvest pesticide use. The Agency reserves the right to change this data requirement if actual commercial practices change to require additional applications.

For a *preharvest* use on wheat, corn soybeans or sorghum after the reproduction stage begins and seed heads are formed, the following flowchart can be used to determine if residue data are required on aspirated grain fractions.



Residue data for ‘‘**aspirated grain fractions**’’ will not normally be needed if the pesticide is applied during the vegetative stage and before the reproduction stage begins and seed heads are formed, unless the plant metabolism and/or processing study shows a concentration of residues of regulatory concern in outer seed coat (e.g., wheat bran, soybean hulls).

(h) **Data reporting - crop field trials.**

(1) **Purpose.**

(i) Crop field trials provide residue chemistry data on the magnitude of the residue in or on RACs to support registration of any pesticide intended for use on a food or feed crop. Residue chemistry data on RACs are used by the Agency to estimate the exposure of the general population to pesticide residues in food, and for setting and enforcing tolerances for pesticide residues in or on raw agricultural foods or feeds.

(ii) Residue chemistry data are also needed to support the adequacy of one or more methods for the enforcement of the tolerance.

(iii) OPPTS guidelines 860.1200 through 860.1520 and the Guidelines on Pesticide Residue Trials developed under the auspices of the Codex Committee on Pesticide Residues (FAO Plant Protection Bulletin, 29:1/2, pp. 12–27, 1981) provide information to aid petitioners/registrants in conducting crop field trials.

(2) **Objective.**

(i) This guideline is designed to aid the petitioner/registrant in generating reports which are compatible with the Agency's review process. While following this guidance is not mandatory, data submitters are encouraged to submit complete reports which can be efficiently reviewed by the Agency.

(ii) The Agency recognizes there are sections in the guideline which do not apply in all cases. Therefore, registrants should exercise scientific judgement in deciding which portions are germane to a specific data submission.

(iii) This guideline is intended to organize the submission of data to facilitate the review process.

(iv) The petitioner/registrant's report on crop field trials on a raw agricultural commodity should include all information necessary to provide a complete and accurate description of field trial treatments and procedures; sampling (harvesting), handling, shipping, and storage of the RAC; storage stability validation (or reference thereto) of the test chemical (and metabolites of toxicological concern) in a plant matrix; residue analyses of field samples for the ''total toxic residue'' and for individual components of toxicological concern); validation (recovery studies) of the residue analytical methodology; reporting of the data and statistical analyses; and, quality control measures/precautions taken to ensure the fidelity of these operations. The following is the suggested format for the report.

(3) Format of the data report. The following describes the order and format for a study report item by item.

(i) Master cover page. Title page and additional documentation requirements (i.e., requirements for data submission and procedures for claims of confidentiality of data) if relevant to the study report should

precede the contents of the study formatted below. These requirements are described in PR Notice 86–5 (see paragraph (l)(19).

(ii) Table of contents. The table of contents should indicate the overall organization of the study, including tables and figures.

(iii) Summary/introduction.

(A) Purpose of studies

(B) Results (including explanations for apparently aberrant, atypical values, or outliers; discussion of geographical representation (major growing areas), seasonal variation (summer/winter, wet/dry, etc.) and representativeness of types and varieties of the RAC

(C) Field procedures

(D) Analytical procedures/instrumentation

(E) Method recovery validation data

(F) Storage stability

(G) Discussion [including Quality Control measures taken; statistical treatment(s) of data; and information on the level(s) of the ‘‘total toxic residue’’ (including any individual component(s) of the residue of special concern) in or on the RAC (specific plant part(s)) arising from the use of the pesticide formulated product on the test crop under specific use conditions. Results should also be correlated to the storage stability study].

(H) Conclusions

(iv) Data tables and other graphic representations.

(A) Summary map (U.S.A. with regions as shown in Attachment 9 of Appendix A. Include outside USA, if applicable) of crop field study sites (by crop)

(B) Summary table(s) of residue results of individual field trials

(C) Graphic representation(s) (e.g., residue decline, figures, flowcharts, etc.)

(D) Summary tables(s) of recovery data via the analytical methodology

(E) Summary table(s) of storage stability validation data

(v) Information/raw data on individual field trials (specifically, each individual field trial report should include the following information):

(A) Test substance (pesticide).

(1) Identification of the test pesticide active ingredient (a.i.), including chemical name, common name (ANSI, BSI, ISO), and company developmental/experimental name.

(2) Identification of the pesticide formulated product(s) used in the field trial, including trade name, type (EC, WP, G, etc.), and amount of active ingredient per gallon, pound, etc., EPA registration number (if available), and manufacturer.

(3) Information on other relevant parameters, as pertinent, (e.g., tank mate(s), spray additive(s), carrier (encapsulating polymer, etc.)).

(4) Other. Any and all additional information the registrant/ petitioner considers appropriate and relevant to provide a complete and thorough description of the test chemical.

(B) Test commodity (RAC).

(1) Identification of the RAC, including type/variety and crop group classification (40 CFR 180.41).

(2) Identification of specific crop part(s) harvested; used in residue analytical methodology validations; and subjected to residue analysis for a determination of the ‘‘total toxic residue.’’

(3) The developmental stage(s), general condition (immature/mature, green/ripe, fresh/dry, etc.) and size(s) of the RAC at time of pesticide application(s and at harvesting(s).

(4) Other. Any and all additional information the registrant/ petitioner considers appropriate and relevant to provide a complete and thorough description of the RAC.

(vi) Test procedures.

(A) A detailed description of the experimental design and procedures followed in the growing of the RAC, application(s) of the pesticide formulated product(s), and harvesting(s) of samples. The information provided, which may be presented on standardized field sheets, should include (in addition to a description of the test substance and test commodity):

(1) Trial identification number.

(2) Cooperator (name and address), test location (region number as shown in Attachments 9 and 10 of Appendix A, county and state - country, if outside USA), and year.

(3) Field trial lay-out (e.g., size and number of control and experimental plots; number of plants per plot/unit area, number of rows per plot, length of rows and row spacing).

(4) Cultural treatment(s) - farming practice (cultivation, irrigation, etc.) and cropping system.

(5) Soil characteristics (name/designation of the soil type. If application rate of the pesticide is dependent on any soil properties such as percent of organic matter, these should also be described).

(6) Method(s) of application (air or ground) of the pesticide formulated product(s), description of the application equipment, type of application (band/broadcast, soil/foliar/ directed, ULV/concentrate/dilute, other), and, calibration of pesticide application equipment, including methods and dates.

(7) Dose rate(s) (amount of active ingredient and formulated product per acre, row, volume, etc.) and spray volume(s) per acre).

(8) Number and timing of application(s) (total number, during dormancy, preplant, preemergence, prebloom, etc., between-application-interval(s), and treatment-to-sampling interval(s) (also known as preharvest interval (PHI).

(9) Other pesticide(s) applied (identity (name and type of formulated product(s), active ingredient(s)), rate(s), date(s), tank-mate or separate, purpose of use).

(10) Climatological data (record of temperature and rainfall during the growing season from the nearest weather station, and wind speed during application). (See guidance on raw data in OPPTS guideline 860.1000.).

(11) Date(s) (planting/sowing/transplanting, as applicable, other significant dates in the growing of the crop (e.g., husk split for tree crops), pesticide application(s), harvest(s)).

(12) Harvest procedures (method of harvesting (mechanical/hand, from the plant/ground/flotation, etc,), type equipment used, number/weight of samples collected per replication and number of replications per treatment level, statistical nature of sampling (e.g., fruit taken from upper, middle, and lower portions of tree exterior and interior), sample coding (cross-referenced to sample history), etc.).

(13) Quality control (control measures/precautions followed to ensure the fidelity of the crop field test).

(14) Other. Any and all additional information the registrant/petitioner considers appropriate and relevant to provide a complete and thorough description of the growing of the RAC, application(s) of the pesticide formulated product(s), and harvesting of samples].

(B) A detailed description of the handling, pre-shipping storage, and shipping procedures for harvested RAC samples. The information provided, which may be presented on a standardized form, should include (in addition to a description of the test substance and the test commodity):

(1) Sample identification (means of labeling/coding);.

(2) Conditions (temperatures, container type(s)/size(s), sample size(s), etc.) and duration of storage before shipping.

(3) Method(s) of packaging for shipment (container type(s)/size(s), sample size(s), ambient/iced, labeling/coding, etc.)).

(4) Means of transport from the field to the laboratory.

(5) Dates (harvest, pre-shipping storage, shipping, and receipt in the laboratory.

(6) Quality control (control measures/precautions followed to ensure the fidelity of harvested samples during handling, pre-shipping storage, and shipping operations).

(7) Other. Any and all additional information the registrant/petitioner considers appropriate and relevant to provide a complete and thorough description of the handling, preshipping storage, and shipping procedures for harvested samples.

(C) A detailed description of the conditions and length of storage of harvested RAC samples following their receipt in the laboratory.

(D) A detailed description of the residue analyses used in determining the ‘‘total toxic residue’’ in RAC field trial and storage stability samples. If the specified information is provided elsewhere within the overall data submission package, it need not be reiterated here. In that case, a reference to the relevant analytical methodology would be sufficient.

(E) Method recovery validation studies should be run concurrently with the residue analyses of crop field trial samples from each individual field trial in order to provide information on the recovery level(s) of the test compounds from the test substrate(s) at various fortification level(s) using the residue analytical methods, and to establish a validated limit of quantification. The following information specific to the method validations, which may be presented on a standardized form, should include:

(1) Experimental design: Identity of test substrate(s) (specific plant part(s)) and test compounds (parent/specific metabolite(s)). Number and magnitude of fortification levels, number of replicate samples per test compound per fortification level, sample coding, control samples, etc.

(2) Fortification procedure: Detail the preparation of the test compound(s) and test substrate(s) and the manner in which the test compound(s) was/were introduced to the test substrate(s).

(3) Dates: Test sample preparation (maceration/extrac-tion/etc.), test compound(s) preparation (standard solution(s) of known concentration), residue analyses.

(4) Residue results: Raw data, ppm found uncorrected (corrected values may also be reported but the basis of correction should be explained), procedure(s) for calculating percent recoveries, recovery levels (range), sensitivity and limit of quantitation.

(5) Other. Any and all additional information the registrant/petitioner considers appropriate and relevant to provide a complete and thorough description of analytical methodology validation procedures.

(vii) Organization of data tables and forms.

(A) Table(s) of residue assay data for specific plant parts analyzed. Residue levels should be reported uncorrected. Corrected values may also be presented but the procedure needs to be explained.

(B) Table(s) on residue recovery values.

(C) Graph(s), as pertinent (e.g., residue decline).

(D) Form(s) containing field trial history information.

(E) Form(s) containing harvesting, shipping, storage information.

(F) Table(s) of weather data if unusual conditions claimed to result in aberrant residues. See raw data guidance in OPPTS guideline 860.1000.

(viii) Certification. A signed and dated certification of authenticity by, and identifying information (typed name, title, affiliation, address, telephone number) of, the personnel responsible for the various phases of this report (e.g., Study Director, Field Supervisor, and Laboratory Supervisor).

(ix) References.

(x) Appendices.

(A) Representative chromatograms, spectra, etc. of reagent blanks, solvent blanks, reference standards, controls, field samples, fortified samples, etc. (cross-referenced to individual field trial study reports).

(B) Reprints of published and unpublished literature, company reports, letters, analytical methodology, etc. cited (or used) by the petitioner/ registrant (unless physically located elsewhere in the overall data report, in which case cross-referencing will suffice).

(C) Other. Any relevant material not fitting in any of the other sections of this report.

(i) **Data reporting - specialty applications.**

(1) **Foreword**. This data reporting section of specialty applications is divided into three parts: 1) Classification of seed treatments and treatment of crops grown for seed use only as non-food or food uses; 2) Postharvest fumigation of crops and processed foods and feeds; 3) Postharvest treatment (except fumigation) of crops and processed foods and feeds. Each part gives the format/outline recommended by the Agency to be used by the petitioner/registrant for reports on the particular specialty application study.

(2) **Format of the data report - Seed treatments.**

For seed treatments to be classified as a non-food use, data from a radiotracer study are needed demonstrating no uptake of radioactivity to the aerial portion and edible root (both human and livestock consumption) portion of the crop. If the radiotracer study demonstrates that the particular seed treatment is a non-food use, no further studies are needed. If the seed treatment is classified as a food use, data as given in the appropriate OPPTS 860 series guidelines are required (e.g., plant metabolism, crop field trials). The following guidance is a format/outline for reporting the radiotracer study determining whether the seed treatment results in uptake of radioactivity to the aerial edible and root portions of the crop.

(i) Master cover page. Title page and additional documentation requirements (i.e., requirements for data submission and procedures for claims of confidentiality of data) if relevant to the study report should precede the contents of the study formatted below. These requirements are described in PR Notice 86–5.

(ii) Table of contents. The table of contents should indicate the overall organization of the study, including tables and figures.

(iii) Introduction.

(A) Background and historical information on the pesticide.

(1) Brief summary of nature of the residue in plants, including the structures of the parent and residues considered to be of toxicological concern.

(B) Purpose of study.

(C) Abstract of study.

(1) Brief summary of application and field procedures.

(2) Results, including unexpected problems.

(3) Conclusions.

(iv) Materials and methods.

(A) Test substance.

(1) Identification of the test pesticide active ingredient (a.i.), including chemical name, common name (ANSI, BSI, ISO), registrant developmental/experimental name and chemical structure.

(2) Description of the radiolabeled test material. Identify the radiolabel and the site of the label. A rationale should be provided for selection of a radiolabel other than ^{14}C and for the site of the label (where possible the ring position should be labeled). The purity, specific activity in Curries/mole and disintegrations per minute per gram (dpm/g) should be reported here.

(3) Identification of the pesticide formulated product(s) in which the radiolabeled pesticide active ingredient was applied, including trade name, type (EC, WP, G, etc.), pounds of active ingredient per gallon, percent a.i. by weight, EPA registration number, and manufacturer.

(4) Physical state and nature of the solvent, carrier, bait, adjuvant or other matrix in which the pesticide was applied.

(B) Test crop.

(1) Identification of the test crop including variety.

(2) Identification of specific crop part(s) harvested and subjected to analysis for radioactivity.

(3) Developmental stage(s), general condition (immature/mature, green/ripe, fresh/dry, etc.), size(s) of the test crop at time of harvest.

(C) Test site.

(1) Description of test site. Overall testing environment (outdoor test plots, greenhouse, plant growth chamber); location (county and state); environmental conditions (temperature, rainfall, sunlight); soil type,

(2) Location (county, state).

(3) Cooperator.

(D) Field trial methods.

(1) Detailed description of application of radiolabeled pesticide to seeds. Information to be reported includes dose rate, pounds active ingredient and formulated product per pounds seed, concentration of treatment solution, volume of application solution per pounds seed, formulation, physical state in which pesticide is applied, diluent, additives, etc., method

of application (hopper box, commercial equipment). The pesticide should be applied at the maximum proposed application rate.

(2) Field trial lay-out. Information to be reported includes size of plots/pots, number of plants per plot/pot, number of plots/pots, number of plants per unit area, length of rows and row spacing.

(3) Farming practice. Information on practices such as cultivation, irrigation, and treatments with other pesticides should be included here.

(4) Harvest procedures, including the number of days between planting and harvesting.

(E) Sampling, handling and storage.

(1) Dates of sampling, shipping, storage, and analyses.

(2) Description of sampling procedure and size of samples.

(3) Handling, preshipping, shipping, post-shipping storage conditions, including storage times.

(F) Analytical procedures/instrumentation.

(1) Description of sample preparation (i.e., dissection, grinding, lyophilization, number of plants contained in one sample, etc.) prior to analyses of radioactivity.

(2) Details of analytical method to measure radioactivity, including descriptions of equipment and instrument parameters.

(G) Quality control. Description of control measures and precautions followed to ensure the fidelity of the field tests, samples and measurement of the residue.

(H) Other pertinent information on materials and methods.

(v) Results and conclusions.

(A) Brief summary of study procedures.

(1) The summary of the study procedures should include the number of field trials, descriptions of the application of the radiolabeled pesticide to the seed (dose rate, method, formulation), the site (greenhouse, outdoors, plant growth chamber), number of days between planting and harvest, number of plants sampled, part of the plant analyzed for radioactivity, and the method of detection.

(B) Results.

(1) Total recovered (i.e., combustible) radioactivity on seeds at time of planting, if measured:

The radioactivity should be reported as:

(a) disintegrations per minute (dpm)

(b) dpm/μg

(c) ppm equivalents (expressed as parent compound). A sample calculation of ppm from radioactive counts should be provided, especially if other units (i.e., not dpm) are used.

(2) The distribution of radioactivity in the treated crop at the time of harvest or sampling:

The data to be reported are the total recovered (i.e., combustible) radioactivity remaining at time of sampling or harvest on the whole plant and on the plant's parts of interest (i.e., the aerial and edible root portions of the plant). The radioactivity for the whole plant and the plant parts should be reported in tabular format as:

(a) dpm

(b) dpm/μg

(c) ppm equivalents (expressed as parent compound).

For the plant parts, the radioactivity should also be expressed as

(d) the percentage of the total recovered radioactivity in the whole plant.

(3) Graphs and figures of the results:

Graphs, if provided, should be accompanied by tables of actual values from which graphs were constructed.

(4) Narrative of results.

Narrative should include a discussion of the quantitative accountability for a majority of the total radioactivity recovered from the aerial and edible root portions of the plant and a discussion of unexpected problems, the way in which they were resolved, and explanations for apparently aberrant, atypical values.

(c) Conclusions.

The petitioner/registrant's conclusion on whether the results of this study and any other relevant studies support a non-food use classification for the seed treatment in question should be given.

(vi) Raw data and information on individual field trials.

(A) Details of radioactive counting data for selected representative samples.

Details should include counting time, total counts recorded, corrected counts, counting efficiencies, other raw data (sample sizes, ppm equivalents found, sensitivity, limit of detection) and other pertinent information needed to check the registrant's calculations.

(B) Description of calculations, including examples.

(C) Description of statistical tests, including examples.

(D) Representative raw data figures.

As applicable, printout sheets, chromatograms, spectra, etc.

(E) Other. Any additional information the registrant considers appropriate and relevant to provide a complete and thorough description of the study.

(vi) Certification.

Certification of authenticity by the Study Director (including signature, typed name, title, affiliation, address, telephone number and date).

(vii) References.

(viii) Appendices.

(A) Reprints of published and unpublished literature, company reports, letters, etc., not expected to be in OPP files, but which the petitioner/registrant feels will aid the review of the study.

(B) Other pertinent information which does not fit in any other section of this outline.

(j) **Data reporting - Postharvest fumigations.**

(1) **Foreword.** Fumigation may be defined as as the act of releasing and dispersing a toxic chemical so that it reaches the organism wholly or primarily in the gaseous or vapor state. Both the raw agricultural commodities and their processed products may be treated postharvest by fumigation.

The report for a study on the postharvest fumigation of raw crops and processed foods should include all information necessary to provide a complete and accurate description of the study.

(2) **Format of the data report - Fumigation.**

(i) Master cover page. Title page and additional documentation requirements (i.e., requirements for data submission and procedures for claims of confidentiality of data) if relevant to the study report should precede the contents of the study formatted below. These requirements are described in PR Notice 86–5.

(ii) Table of contents. The table of contents should indicate the overall organization of the study, including tables and figures.

(iii) Introduction.

(A) Background and historical information on the pesticide.

(1) Brief summary of nature of the residue in plants, including the structures of the parent and residues considered to be of toxicological concern.

(B) Purpose of study.

(C) Abstract of study.

(1) Brief summary of application procedures.

(2) Results, including unexpected problems.

(3) Conclusions.

(iv) Materials and methods.

(A) Test Substance

(1) Identification of the test pesticide active ingredient (a.i.), including chemical name, common name (ANSI, BSI, ISO), registrant developmental/experimental name and chemical structure.

(2) Identification of the pesticide formulated product(s) in which the pesticide active ingredient was applied, including trade name, type (ED, WP, G, etc.), pounds of active ingredient per gallon, percent a.i. by weight, EPA registration number and manufacturer.

(3) Information on the matrix in which the formulated pesticide was applied and on any additives.

(4) Physical/chemical parameters on the test substance.

(B) Test raw or processed commodity.

(1) Identification of the raw or processed test commodity, including variety.

(2) Identification cf specific crop part(s) harvested.

(3) Developmental stage(s), general condition (immature/mature, green/ripe, fresh/dry, etc.), size(s) of the test commodity at time of fumigation.

(4) Size and kind of containers holding the commodity (e.g. wood, burlap, etc.).

(5) Information on whether the raw or processed commodity, or its storage container, had been treated prior to the test postharvest treatment, including application rates, PHIs, and the residue prior to the test postharvest treatment.

(C) Test site.

(1) Description of fumigation chamber.

Information to be reported includes:

(a) Type of fumigation chamber (grain elevator and flat storage, tarpaulin covering, shophold, fumigation vault, vacuum chamber, etc.).

(b) Size and geometry of fumigation chamber.

(c) Measures taken to seal the fumigation chamber (e.g., covering surfaces with asphalt paper or plastic tarpaulins, sealing of vents, windows, cracks, etc.).

(d) Temperature inside the chamber.

(e) The relative size of the chamber as compared to the commodity load.

(2) Location of fumigation chamber.

Information to be reported includes:

(a) County and state.

(b) Enviromental conditions, if applicable (temperature, wind, humidity

(c) Cooperator.

(D) Application of the pesticide.

(1) Type of fumigant dispensing system and method of fumigant volatilization.

(2) Measures taken to hasten gas circulation.

(3) Dose rate, exposure time, temperature, and pressure;

(4) Layout of the fumigation chamber (i.e., discharge points and positioning of circulating fans/blowers in relation to arrangement of commodities, size of stacks of commidities, etc.).

(5) Number and date(s) of application(s).

(6) Formulation.

(E) Aeration of the commodities.

(1) The aeration time and the dates of the aeration.

(2) Description of aeration procedures inside (e.g., removal of seals and covers, opening of doors and windows, use of exhaust fans and air suction system) and outside the fumigation chamber.

(3) Description of any aeration following sampling.

(F) Sampling, handling, and storage.

(1) Dates of sampling, shipping, storage and, analyses.

(2) Description of sampling procedure, including the location of the sampling (e.g., top, bottom or side outer layer or center of stack; side or middle of chamber), size of the samples, and measures taken to prevent desorption of the fumigant during sampling.

(3) Handling, preshipping, shipping, and post-shipping storage conditions, including storage times, special measures taken to prevent desorption of the fumigant during the time between sampling and analysis, and description of sample containers and storage temperature.

(G) Analytical procedures/instrumentation.

(1) Description of sample preparation (compositing, subsampling, grinding, extraction, etc.) and measures taken to prevent desorption of the fumigant during sample preparation.

(2) Detaiis of analytical method to measure residue, including descriptions of equipment/instrumentation and instrument parameters.

(H) Quality control.

Description of control measures and precautions to ensure the fidelity of the test, samples and measurement of the residue.

(I) Any other pertinent information on material and methods.

(v) Results and conclusions.

(A) Brief summary of the study procedures.

The summary of the study procedures should include the number of trials, the commodities, whether the commodities had been previously treated with the test active ingedient, descriptions of the fumigations and fumigation chambers, the fomulation, aeration time, and the method of detection.

(B) Results of analyses of treated and control samples and fortified samples.

(1) Tables of the results.

Residue data should be given in a tabular format, providing the following information:

(a) Commodity.

(b) Plant part.

(c) Type of fumigation chamber.

(d) Dose.

(e) Exposure time.

(f) Temperature.

(g) Aeration time.

(h) Residue; residue testing should extend beyond sampling immediately after the label specified aeration to include studies to follow the rate of residue decline that could be expected under various shipping and storage conditions and temperature.

(2) Graphs and figures of the results.

Graphs, if provided, should be accompanied by tables of actual values from which graphs were constructed.

(3) Narrative on the results.

Narrative should include a discussion of unexpected problems and ways in which they were resolved and explanations for apparently aberrant, atypical values.

(E) Conclusions on the appropriate tolerance(s) for the proposed use(s).

(vi) Raw data and information on individual trials.

(A) Raw data tables for residue analyses of treated, control and fortification recovery samples and standards.

(B) Representative raw data figures.

(1) As applicable, printouts, spectra, chromatograms of treated samples, control samples, fortified samples and standards, etc.

(2) Calibration curves.

(C) Description of calculations, including examples.

(D) Description of statistical tests, including examples.

(E) Other. Any additional information the petitioner/registrant considers appropriate and relevant to provide a complete and thorough description of the study.

(vii) Certification.

Certification of authenticity by the Study Director (including signature, typed name,title, affiliation, address, telephone number, and date).

(viii) References.

(ix) Appendices.

(A) Reprints of published and unpublished literature, company reports, letters, etc., not expected to be in OPP files, but which the petitioner/ registrant feels will aid the review of the study.

(B) Other pertinent information which does not fit in any other section of this outline.

(k) **Data reporting - Postharvest treatment (except fumigation).**

(1) **Foreword.** Post-harvest treatments of foods and feeds are applied by various means, including dips, drenches, mechanical foamers, and spray and brush applicators. The pesticide may be applied directly (to the commodity) or indirectly (to the storage bin). Often, the application of a wax coating on the commodity is involved. Both the raw agricultural commodity and its processed product may be treated postharvest. The report for a study on the post-harvest treatment of raw crops and processed foods and feeds should include all information necessary to provide a complete and accurate description of the study.

(2) **Format of the data report**.

(i) Master cover page. Title page and additional information requirements (i.e., requirements for data submission and procedure for claims of confidentiality of data) if relevant to the study report should precede the content of the study formatted below. These requirements are described in PR Notice 86–5.

(ii) Table of contents. The table of contents should indicate the overall organization of the study, including tables and figures.

(iii) Introduction.

(A) Background and historical information on the pesticide.

(1) Brief summary of nature of the residue in plants, including the structures of the parent and the residues considered to be of toxicological significance.

(B) Purpose of study.

(C) Abstract of study.

(1) Brief summary of application procedures.

(2) Results, including unexpected problems.

(3) Conclusions.

(iv) Materials and methods.

(A) Test Substance.

(1) Identification of the test pesticide active ingredient (a.i.), including chemical name, common name (ANSI, BSI, ISO), registrant developmental/experimental name and chemical structure.

(2) Identification of the pesticide formulated product(s) in which the pesticide active ingredient was applied, including trade name, type (EC, WP, G, etc.), pounds of active ingredient per gallon, percent a.i. by weight, EPA registration number and manufacturer.

(3) Information on the matrix (e.g., water, wax) in which the formulated pesticide was applied and on any additives.

(B) Test raw or processed commodity.

(1) Identification of the raw or processed test conmodity, including variety.

(2) Identification of specific crop part(s) treated and analyzed.

(3) Developmental stage(s), general condition (mature/immature, green/ripe, fresh/dry, etc.), size(s) of the test commodity at time of treatment.

(4) Information on whether the commodity or storage container had been treated with the test active ingredient prior to the test postharvest treatment, including application rates, PHIs, and the residue prior to the test postharvest treatment.

(C) Test site.

(1) Description of test site.

Overall testing environment (outdoor, indoor, climate controlled packinghouse, etc.), temperature;

(2) Location (county, state).

(3) Cooperator.

(D) Application of the pesticide.

(1) Physical state in which the pesticide was applied.

(2) Description cf method/equipment for pesticide application e.g., direct (applied to commodity) or indirect (applied to storage container), dips, drenches, mechanical towers, spray applicators, brush applicators, wax applicators.

(3) Pounds active ingredient and formulation per pounds treated commodity, concentration of treatment solution, volume of treatment per pounds treated commodity, exposure time, number of treatments, and temperature of solution.

(4) Description of post-harvest practices accompanying the post-harvest treatment such as application of wax coatings after treatment, detergent washes, and rinses, including number, timing, and volume.

(5) Date(s) of application(s).

(6) Formulation.

(F) Sampling, handling, and storage.

(1) Dates of sampling, shipping, storage, and analyses.

(2) Description of sampling procedure and size of the samples.

(3) Handling, pre-shipping, shipping, and post-shipping storage conditions, including storage time.

(G) Analytical procedures/instrumentation.

(1) Description of sample preparation (compositing, subsampling, grinding, extraction, etc.).

(2) Details of analytical method to measure residue, including descriptions of equipment/ instrumentation and instrument parameters.

(H) Quality control.

Description of control measures and precautions to ensure the fidelity of the field test, samples and measurement of the residue.

(I) Any other pertinent information on materials and methods.

(v) Results and conclusions.

(A) Brief summary of study procedures.

The summary of the study procedures should include the number of trials, the commodities, whether the commodities had been previously treated with the test active ingredient, description of the post-harvest treatment

(e.g., concentration, exposure time, temperature), the formulation, and the method of detection.

(B) Results of analyses of treated and control samples and fortified samples.

(1) Tables of the results.

Residue data should be given in a tabular format, providing the following information, as applicable:

(A) Commodity.

(B) Plant part.

(C) Method/equipment for pesticide application.

(D) Pounds active ingredient per pounds commodity.

(E) Concentration of treatment solution.

(F) Volume treatment solution per pounds commodity.

(G) Exposure time.

(H) Number of treatments.

(I) Other pertinent information affecting the level of residue (e.g., use of wax, rinse, volume and time of rinse).

(J) Formulation.

(K) Residue; residue testing should provide information on the rate of residue decline that could be expected under various shipping and storage conditions and temperature.

(2) Graphs and figures of the results:

Graphs, if provided, should be accompanied by tables of actual values from which graphs were constructed.

(3) Narrative on the results:

Narrative should include a discussion of unexpected problems and ways in which they were resolved and explanations for apparently aberrant, atypical values.

(C) Conclusions on the appropriate tolerance(s) for the proposed use(s).

(vi) Raw data and information on individual trials.

(A) Raw data tables for residue analyses of treated, control and fortification recovery samples, and standards.

(B) Representative raw data figures.

(1) As applicable, printouts, spectra, chromatograms of treated samples, control samples, fortified samples and standards, etc.

(2) Calibration curves.

(C) Description of calculations, including examples.

(D) Description of statistical tests, including examples.

(E) Other.

Any additional information the petitioner/registrant considers appropriate and relevant to provide a complete and thorough description of the study.

(vii) Certfication.

Certification of authenticity by the Study Director (including signature, typed name, title, affiliation, address, telephone number and date).

(viii) References.

(ix) Appendices.

(A) Reprints of published and unpublished literature, company reports,letters, etc., not expected to be in OPP files, but which the registrant feels will aid the review of the study.

(B) Other pertinent information which does not fit in any other section of this outline.

(l) **References.** The source material for this guideline was taken directly from thefollowing set of documents.

(1) U.S. Environmental Protection Agency, Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry. EPA Report No. 540/9–82–023, October, 1982, (Available from National Technical Information Service, Springfield, VA)

(2) U.S. Environmental Protection Agency, Pesticide Reregistration Rejection Rate Analysis - Residue Chemistry; Follow-up Guidance for: Generating Storage Stability Data; Submission of Raw Data; Maximum Theoretical Concentration Factors; Flowchart Diagrams. EPA Report No. 737–R–93–001, February, 1993.

(3) U.S. Environmental Protection Agency, Pesticide Reregistration Rejection Rate Analysis - Residue Chemistry; Follow-up Guidance for: Updated Livestock Feeds Tables; Aspirated Grain Fractions (Grain Dust); A Tolerance Perspective; Calculating Livestock Dietary Exposure; Number and Location of Domestic Crop Field Trials. EPA Report No. 737–K–94–001, June, 1994.

(4) U.S. Environmental Protection Agency, Pesticide Reregistration Rejection Rate Analysis - Residue Chemistry; EPA Report No. 738–R–92–001, June, 1992.

(5) U.S. Environmental Protection Agency, FIFRA Accelerated Reregistration - Phase 3 Technical Guidance. EPA Report No. 540/09–90–078. (Available from National Technical Information Service, Springfield, VA).

(6) U.S. Environmental Protection Agency, Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, Series 171–4; Addendum No. 2 on Data Reporting, Magnitude of the Residue: Crop Field Trials, EPA Report No. 540/09–86–151. (Available from National Technical Information Service, Springfield, VA).

(7) U.S. Environmental Protection Agency, Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, Series 171–4; Addendum No. 5 on Data Reporting, Specialty Applications, EPA Report No. 540/09–88–008. (Available from National Technical Information Service, Springfield, VA).

(8) U.S. Department of Agriculture, Pesticide Analytical Methods (PAM), Vols. I and II, 1993. (Available from National Technical Information Service).1

(9) American Crop Protection Association (ACPA); NACA Recommendations for Residue Site Selection and Number of Field Trials, September, 1992.

(10) Federal Register Notice, Vol. 60, Number 95, pp. 26625–26643, May 17, 1995: Pesticide Tolerances; Revision of Crop Groups.

(11) U.S. Department of Agriculture, Agricultural Statistics, 1991.

(12) U.S. Department of Commerce, Census of Agriculture, 1987.

(13) National Academy of Sciences, Pesticides in the Diets of Infants and Children, 1993, National Research Council, Washington, D.C.

(14) L.H. Keith et al, Principles of Environmental Analysis, Analytical Chemistry. 55: 2210–2218 (1983).

(15) U.S. Environmental Protection Agency, Pesticide Registration Notice, PR 93–2, Waiver of Crop Field Trial Data for Aerial Applications, February 11, 1993.

(16) Grain Quality Improvement Act (GQIA), 1986.

(17) Federal Register Notice, Vol. 52, Number 125, pp. 24414–24441, June 30, 1987.

(18) Association of American Feed Control Officials (AAFCO), 1993 Official Publication, 1993.

(19) U.S. Environmental Protection Agency, Pesticide Registration Notice PR 86–5, Standard Format for Data Submitted under the FIFRA and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), May 3, l986.

APPENDIX A–TABLES AND ATTACHMENTS FOR GUIDANCE ON NUMBER AND LOCATION OF DOMESTIC CROP FIELD TRIALS

List of Attachments/Tables in Appendix A

Table 1–Minimum Numbers of Crop Field Trials and Treated Samples for Tolerances in Individual Crops

Table 2–Required Numbers of Field Trials for Crop Groups in 180.41

Table 3–Required Numbers of Field Trials for Proposed Crop Subgroups in 180.41

Table 4–Required Numbers of Field Trials for Crop ‘‘Groups’’ in 180.1(h)

Table 5–Suggested Distribution of Field Trials by Region for Crops Requiring <3 Trials

Table 6–Regional Distribution of Crop Production

Attachment 7: Methodology for Determining Number of Field Trials

Attachment 8: Codex ‘‘Guidelines on Minimum Sample Sizes for Agricultural Commodities from Supervised Field Trials for Residue Analysis’’

Attachment 9: Map of Growing Regions for Trial Distribution

Attachment 10: Border Definitions of Regions

Attachment 11: Number of Field Trials Required for Tolerances with Geographically Restricted Registration and for 24(c) Special Local Needs Registrations

Table 1: Minimum Numbers of Crop Field Trials and Treated Samples For Tolerances on Individual Crops

Following the procedure explained in the body of this guideline and in Attachment 7, this table specifies the minimum numbers of field trials and treated samples required to obtain tolerances on individual crops. For those crops requiring (insert replacement note for greater than equal to symbol) 8 trials in this table, a 25% reduction in the number of trials is acceptable for uses resulting in no quantifiable residues providing certain criteria are met (see document for details). The same reduction is accept-

able for representative commodities that are being used to obtain crop group tolerances (see Table 2) and some crop subgroup tolerances (see Table 3).

[NOTE: Application of both 25% reductions (residues <LOQ and crop group) to a given crop will not be acceptable.]

The numbers in this table represent the minimum number of acceptable trials reflecting the label use pattern producing the highest residue. Trials reflecting other use patterns or which for some reason do not generate viable samples will not be counted. In addition, these numbers of trials are predicated upon only one formulation type being requested for use on the crop. If additional types of formulations are desired, additional data may be needed as discussed in the Formulations section of this guideline.

A minimum of two treated samples is required from each field trial for crops requiring <3 trials. For crops requiring <3 trials, a minimum of four treated samples from four independently treated plots is required for each trial - two samples reflecting the maximum proposed application rate (1x) and two reflecting a 2x rate. As discussed in the Sampling Requirements section of this guideline, each composite sample should be collected by a separate run through a treated plot. Splitting one sample from a plot or conducting two analyses on one sample will not be an acceptable alternative to separately collecting and analyzing two samples. Multiple analyses of a single sample or of subsamples constitute the equivalent of only one data point.

Table 1—Minimum Numbers of Crop Field Trials and Treated Samples for Tolerances on Individual Crops

Crop	Minimum No. of Trials	Minimum No. of Treated Samples
Acerola (Barbados cherry)	1	4
Alfalfa	12	24
Almond	5	10
Apple, Sugar	2	8
Apple	16	32
Apricot	5	10
Arracacha	2	8
Artichoke, Globe	3 or 2*	6 or 8*
Artichoke, Jerusalem	3	6
Asparagus	8	16
Atemoya	1	4
Avocado	5	10
Banana	5	10
Barley	12	24
Bean, Dried[1]	12	24
Bean, Edible Podded[1]	8	16
Bean, Lima, Dried	3	6
Bean, Lima, Succulent	8	16
Bean, Mung	3 or 2*	6 or 8*
Bean, Snap	8	16
Bean, Succulent Shelled[1]	8	16
Beet, Garden	5	10

Table 1—Minimum Numbers of Crop Field Trials and Treated Samples for Tolerances on Individual Crops—Continued

Crop	Minimum No. of Trials	Minimum No. of Treated Samples
Blackberry	[2]3	[2]6
Blueberry	8	16
Bok choi	2	8
Boysenberry	2	8
Broccoli	8	16
Broccoli, Chinese (gailon)	2	8
Brussels Sprouts	3 or 2*	6 or 8*
Buckwheat	5	10
Cabbage	8	16
Cabbage, Chinese	3	6
Cacao Bean (cocoa)	3	6
Calabaza	2	8
Calamondin	1	4
Canola	8	16
Cantaloupe	8	16
Carambola	2	8
Carob	3	6
Carrot	8	16
Cassava, bitter or sweet	2	8
Cauliflower	8	16
Celery	8	16
Cherry, Tart	8	16
Cherry, Sweet	8	16
Chestnut	3	6
Chickpea (garbanzo bean)	3	6
Chicory	2	8
Clover	12	24
Coconut	5	10
Coffee	5	10
Collards	5	10
Corn, Field	20	40
Corn, Pop	3	6
Corn, Sweet	12	24
Cotton	12	24
Crabapple	3	6
Cranberry	5	10
Cress, Upland	1	4
Cucumber	8	16
Currant	2	8
Dandelion	1	4
Date	3 or 2*	6 or 8*
Dill (dill seed, dillweed)	2	8
Eggplant	3	6
Elderberry	3	6
Endive (escarole)	3	6
Fig	3 or 2*	6 or 8*
Filbert (hazelnut)	3 or 2*	6 or 8*
Flax	5	10
Garlic	3	6
Genip	1	4
Ginger	2	8
Ginseng	1	4
Gooseberry	3	6
Grapefruit	8	16
Grape	12	24

Table 1—Minimum Numbers of Crop Field Trials and Treated Samples for Tolerances on Individual Crops—Continued

Crop	Minimum No. of Trials	Minimum No. of Treated Samples
Grasses (crop group) (also see Table 2)	12	24
Guar	3 or 2*	6 or 8*
Guava	2	8
Hops	3	6
Horseradish	3	6
Huckleberry	3	6
Kale	3	6
Kiwi fruit	3 or 2*	6 or 8*
Kohlrabi	3	6
Kumquat	1	4
Leek	3	6
Lemon	5	10
Lentil	3	6
Lettuce, Head	8	16
Lettuce, Leaf	8	16
Lime	3	6
Loganberry	2	8
Longan	1	4
Lotus Root	1	4
Lychee	1	4
Macadamia Nut	3 or 2*	6 or 8*
Mamey Sapote	2	8
Mandarin (tangerine)	5	10
Mango	3 or 2*	6 or 8*
Melon, Casaba	3	6
Melon, Crenshaw	3	6
Melon, Honeydew	5	10
Millet, Proso	5	10
Mint[3]	5	10
Mulberry	3	6
Mushrooms	3	6
Muskmelons[4]	8	16
Mustard, Chinese	2	8
Mustard Greens	[5]5	[5]10
Nectarine	8	16
Oat	16	32
Okra	5	10
Olive	3	6
Onion, Dry Bulb	8	16
Onion, Green	3	6
Orange, Sour and Sweet	16	32
Papaya	3 or 2*	6 or 8*
Parsley	3	6
Parsnip	3	6
Passion Fruit	2	8
Pawpaw	3 or 2*	6 or 8*
Peach	12	24
Peanut	12	24
Peanut, Perennial	3	6
Pear	8	16
Pea, Austrian Winter	3	6
Pea, Chinese	1	4
Pea, Dried[1]	5	10
Pea, Edible Podded[1]	3	6
Pea, Garden, Dried	3	6

Table 1—Minimum Numbers of Crop Field Trials and Treated Samples for Tolerances on Individual Crops—Continued

Crop	Minimum No. of Trials	Minimum No. of Treated Samples
Pea, Garden, Succulent	8	16
Pea, Succulent Shelled[1]	8	16
Pecan	5	10
Pepper, Bell	8	16
Pepper, Non-bell	3	6
Persimmon	3 or 2*	6 or 8*
Pimento	2	8
Pineapple	8	16
Pistachio	3	6
Plantain	3 or 2*	6 or 8*
Plum	8	16
Pomegranate	3 or 2*	6 or 8*
Potato	16	32
Pumpkin	5	10
Quince	3 or 2*	6 or 8*
Radish, Oriental (daikon)	2	8
Radish	5	10
Raspberry, Black and Red	[2]3	[2]6
Rhubarb	2	8
Rice	16	32
Rice, Wild	5	10
Rutabaga	3	6
Rye	5	10
Safflower	5	10
Sainfoin	3	6
Salsify	3	6
Sesame	3	6
Shallot	1	4
Sorghum, Grain (milo)	12	24
Soybean (dried)	20	40
Spinach	8	16
Squash, Summer	5	10
Squash, Winter	5	10
Strawberry	8	16
Sugar Beet	12	24
Sugarcane	8	16
Sunflower	8	16
Sweet Potato	8	16
Swiss Chard	3	6
Tangelo	3	6
Tanier	2	8
Taro (dasheen)	2	8
Tobacco	3	6
Tomato	16	32
Turnip root	5	10
Turnip top	5	10
Walnut, Black and English	3	6
Watercress	2	8
Watermelon	8	16
Wheat	20	40
Yam, True	3	6

* For these crops registrants/petitioners have the option of doing 3 trials with two treated samples (1x rate) per trial or 2 trials with four treated samples (two at 1x rate, two at 2x rate) per trial.

[1] These bean/pea commodities include more than one type of bean/pea. The specific commodities included in each of these groups are shown below. The specific representative commodity for which field trials should be run in each case are those representative commodities provided in the proposed crop subgroup Federal Register notice. *bean, edible podded:* include those commodities listed in the proposed crop subgroup 6-A as Phaseolus spp., Vigna spp., jackbeans, soybeans (immature seed) and sword beans. *pea, edible podded:* include those commodities listed in the proposed crop subgroup 6-A as Pisum spp. and pigeon peas. *bean, succulent shelled:* include those commodities listed in the proposed crop subgroup 6-B as Phaseolus spp., Vigna spp. and broad beans. *pea, succulent shelled:* include those commodities listed in the proposed crop subgroup 6-B as Pisum spp. and pigeon pea. *bean, dried:* include those commodities listed in the proposed crop subgroup 6-C as Lupinus spp., Phaseolus spp., Vigna spp., guar and lablab beans. *pea, dried:* include those commodities listed in the proposed crop subgroup 6-C as Pisum spp., lentils and pigeon peas.

[2] A minimum of five trials (and 10 samples) is required on any one blackberry or any one raspberry if a tolerance is sought on ''caneberries'' (see Table 3 or Table 4). A minimum of three trials (and six samples) is required if a tolerance is sought only on blackberries or only on raspberries.

[3] A tolerance for mint may be obtained using residue data for spearmint and/or peppermint. If a tolerance is sought for either spearmint or peppermint separately, five trials are still required.

[4] A tolerance for muskmelons may be obtained using residue data for cantaloupes.

[5] A minimum of eight trials (and 16 samples) is required on mustard greens if a tolerance is sought on the crop subgroup leafy Brassica greens (see Table 3).

Table 2.—Required Numbers of Field Trials For Crop Groups (180.41)

Crop Group	Representative	Number of Field Trials for Commodity if Not Part of Crop Group	Number of Field Trials for Commodity as Part of Crop Group
1) Root and Tuber Vegetables.	carrot	8	6
	potato	16	12
	radish	5	5
	sugar beet	12	9
			Total = 32
2) Leaves of Root and Tuber Vegetables (Human Food or Animal Feed)	turnip	5	5
	sugar beet or gardern beet	12	9
			Total = 14
3) Bulb Vegetables (Allium spp.)	green onion	3	3
	dry bulb onion	8	6
			Total = 9
4) Leafy Vegetables (Except Brassica Vegetables)	leaf lettuce	8	6
	head lettuce	8	6
	celery	8	6
	spinach	8	6
			Total = 24
5) Brassica (Cole) LeafyVegetables	broccoli orcauliflower	8	6
	cabbage	8	6
	mustard greens	5	5
			Total = 17

Table 2.—Required Numbers of Field Trials For Crop Groups (180.41)—Continued

Crop Group	Representative	Number of Field Trials for Commodity if Not Part of Crop Group	Number of Field Trials for Commodity as Part of Crop Group
6) Legume Vegetables (Succulent or Dried)	bean (Phaseolu spp.), succulent	NA	[1]12
	bean (Phaseolus spp.), dried	12	9
	pea (Pisum spp.), succulent	NA	[2]9
	pea (Pisum spp.), dried	5	5
	soybean	20	15
			Total = 50
7) Foliage of Legume Vegetables	bean (any cultivar)	8	6
	field pea[3]	5	5
	soybean	20	15
			Total = 26
8) Fruiting Vegetables (Except Cucurbits)	tomato	16	12
	pepper (bell + one cultivar non-bell)	11 (8 + 3)	9 (6 + 3)
			Total = 21
9) Cucurbit Vegetables	cucumber	8	6
	melon (cantaloupe or muskmelon)	8	6
	summer squash	5	5
			Total = 17
10) Citrus Fruits (Citrus spp., Fortunella spp.)	orange, sweet	16	12
	lemon	5	5
	grapefruit	8	6
			Total = 23
11) Pome Fruits	apple	16	12
	pear	8	6
			Total = 18
12) Stone Fruits	sweet or tart cherry	8	6
	peach	12	9
	plum (or fresh prune)	8	6
			Total = 21
13) Berries	blackberry (or raspberry)	3	3
	blueberry, highbush	8	6
			Total = 9

Table 2.—Required Numbers of Field Trials For Crop Groups (180.41)—Continued

Crop Group	Representative	Number of Field Trials for Commodity if Not Part of Crop Group	Number of Field Trials for Commodity as Part of Crop Group
14) Tree Nuts	almond	5	5
	pecan	5	5
			Total = 10
15) Cereal Grains	fresh sweet corn	12	9
	dried field corn	20	15
	rice	16	12
	sorghum	12	9
	wheat	20	15
			Total = 60
16) Forage, Fodder and Straw of Cereal Grains	corn	20	15
	wheat	20	15
	any other cereal grain	16	12
			Total = 42
17) Grass Forage, Fodder, and Hay	Bermuda grass, bluegrass, and bromegrass or fescue	12 (4 trials for each variety)	Total = 12
18) Non-Grass Animal Feeds (Forage, Fodder, Straw, and Hay)	alfalfa	12	9
	clover	12	9
			Total = 18
19) Herbs and Spices[3]	basil (fresh and dried)	3	3
	chive	3	3
	dill seed or celery seed	2	3
	black pepper	3	3
			Total = 12

[1] Twelve total field trials are required, 6 for an edible podded bean, and 6 for a succulent shelled bean.

[2] Nine total field trials are required, 3 for an edible podded pea, and 6 for a succulent shelled pea.

[3] The required number of field trials for field peas takes into account the total acreage of various types of peas and lentils.

Table 2[3].—Required Numbers of Field Trials for Crop Groups (180.41)

The number of field trials required for crop groups is provided in Table 2. For crop groups, the required number of field trials shown in Table 1 should be done for each representative commodity, except that 25% fewer trials are required for representative commodities normally requiring 8 or more trials. This procedure does not necessarily apply to the crop subgroups shown in the Table below since there are fewer representative commodities in many cases (see Pesticide Tolerances; Revision of Crop Groups; Federal Register, Vol. 60, No. 95 pp. 26625–26643). The table below and the corresponding footnotes describe the required numbers of field trials for crop subgroups.

Crop Group	Crop Subgroup	Representative Commodities	Other Commodities[1]	Production Acres[8] (x1000)	% Consumption
1A. Root Vegetables[3]	carrot		98	0.322	6
	radish		46	0.003	5
	sugar beet		1350	0.617	9
		Total	1494	0.942	20
1B. Root Vegetables Except Sugar Beets[3]	carrot		98	0.322	6
	radish		46	0.003	5
		beet, garden	13	0.042	
		turnip	20	0.043	
		Total	177	0.410	11
1C. Tuberous and Corm Vegetables[4]	potato		1310	2.091	16
		sweet potato[8]	90.5	0.072	
		Total	1400	2.163	16
1D. Tuberous and Corm Vegetables Except Potato[4]	sweet potato[8]		90.5	0.072	8
4A. Leafy Greens[3]	lettuce, head		240	0.394	6
	lettuce, leaf		51	0.025	6
	spinach		36	0.081	6
		Total	327	0.500	18
4B. Leaf Petioles[4]	celery[8]		36	0.114	8
5A. Head and Stem[3] Brassica	cabbage[8]		98.7	0.182	6
	cauliflower (or broccoli)		65 (115)	0.029 (0.091)	6
		Total	278.7	0.302	12
5B. Leafy Brassica Greens[7]	mustard greens		9.7	0.027	[7]5
		cabbage, Chinese	8.7	0.007	
		collards	15	0.035	
		kale	6.2	0.003	
		Total	39.6	0.072	[7]8

Table 2[3].—Required Numbers of Field Trials for Crop Groups (180.41)—Continued

The number of field trials required for crop groups is provided in Table 2. For crop groups, the required number of field trials shown in Table 1 should be done for each representative commodity, except that 25% fewer trials are required for representative commodities normally requiring 8 or more trials. This procedure does not necessarily apply to the crop subgroups shown in the Table below since there are fewer representative commodities in many cases (see Pesticide Tolerances; Revision of Crop Groups; Federal Register, Vol. 60, No. 95 pp. 26625–26643). The table below and the corresponding footnotes describe the required numbers of field trials for crop subgroups.

Crop Group	Crop Subgroup	Representative Commodities	Other Commodities[1]	Production Acres[8] (x1000)	% Consumption
6A. Edible Podded Legume Vegetables[3]	one succulent cultivar of edible podded bean		289	0.372	6
	one succulent cultivar of edible podded pea		unknown	unknown	3
		Total	289	0.372	9
6B. Succulent, Shelled Pea and Bean[3]	one succulent shelled cultivar of bean		51	0.048	6
	one garden pea		314	0.319	6
		Total	365	0.367	12
6C. Dried, Shelled Pea and Bean, Except Soybean[3]	one dried cultivar of bean		1750	0.267	9
	one dried cultivar of pea		395	0.005	5
		Total	2145	0.272	14
7A. Foliage of Legume Vegetables Except Soybeans[3]	any cultivar of bean		2090	0	6
	field pea		709	0	5
		Total	2799	0	11
9A. Melons[4]	cantaloupe		130	0.083	8
		watermelon	193	0.142	
		melon, honeydew	29	0.034	
		Total	352	0.259	8
9B. Squash/Cucumber[3]	one cultivar summer squash		29	0.059	5
	cucumber		130	0.134	6
		pumpkin	41	0.008	
		winter squash	29	0.060	
		Total	229	0.261	11
13A. Caneberry (Blackberry and Raspberry)[5]	any one blackberry[8] (or any one raspberry)		7.9 (15)	0.018 (0.006)	3 (3)

Table 2[3].—Required Numbers of Field Trials for Crop Groups (180.41)—Continued

The number of field trials required for crop groups is provided in Table 2. For crop groups, the required number of field trials shown in Table 1 should be done for each representative commodity, except that 25% fewer trials are required for representative commodities normally requiring 8 or more trials. This procedure does not necessarily apply to the crop subgroups shown in the Table below since there are fewer representative commodities in many cases (see Pesticide Tolerances; Revision of Crop Groups; Federal Register, Vol. 60, No. 95 pp. 26625–26643). The table below and the corresponding footnotes describe the required numbers of field trials for crop subgroups.

Crop Group	Crop Subgroup	Representative Commodities	Other Commodities[1]	Production Acres[8] (x1000)	% Consumption
		Total	22.9	0.024	5
13B. Bushberry[4]	blueberry, highbush		59	0.017 (consumption for nonnursing infants = 0.043%)	8
19A. Herbs[6]	basil, fresh and dried				3
	chive				3
		Total	2.75	0.014	6
19B. Spices[6]	black pepper				3
	celery seed or dill seed				3
		Total	2.75	0.014	6

[1] The column ''other commodities'' only includes commodities which account for >5% of the acreage estimates for the representative commodities.

[2] A minimum of 3 field trials is required for any representative commodity.

[3] The number of required field trials for these crops was determined in the same manner as for crop groups.

[4] For each of these crop subgroups, the normal number of field trials required for the representative commodity is required for the crop subgroup.

[5] The required number (five) of field trials for Caneberries was determined using the total acreage and consumption estimates for blackberries and raspberries, and then applying the same criteria as used for determining the number of required field trials for individual commodities. A minimum of three field trials is required if a tolerance is sought for either blackberries or raspberries separately.

[6] For the subgroups ''Herbs'' and ''Spices'', the minimum number of required field trials (3) was required for each representative commodity.

[7] The required number of field trials for Leafy Brassica Greens was determined using the total acreage and consumption estimates for the major commodities in the subgroup (since mustard greens represents a relatively small fraction of this total), and then applying the same criteria as used for determining the number of required field trials for individual commodities. Therefore, a minimum of eight trials is required if a tolerance is sought on Leafy Brassica Greens. If a tolerance on only ''mustard greens'' is desired, a minimum of five trials is required (see Table 1).

[8] Acreage information (given in thousands of acres) and consumption for the following commodities include values for both the commodity itself, and the acreages and consumptions of other commodities for which the tolerance would apply as defined in 40 CFR 180.1(h): blackberries: blackberries (6.7), boysenberries (1.2); cabbage: cabbage (90), Chinese cabbage (napa) (8.7);celery: celery (36), fennel (only consumption data available); sweet potatoes: sweet potatoes (87), yams (3.5).

The Code of Federal Regulations (40 CFR 180.1(h)) states the following:

Tolerances and exemptions established for pesticide chemicals in or on the general category of raw agricultural commodities listed in column A apply to the corresponding specific raw agricultural commodities listed in column B. However, a tolerance or exemption for a specific commodity in column B does not apply to the general category in Column A.

This section of the CFR addresses two distinct situations. In the first situation, a specific commodity is included in both columns A and B. Residue data for that commodity support a registration or tolerance for itself as well as for the additional items listed in column B. These include the following column A commodities: alfalfa, bananas, blackberries, broccoli, cabbage, celery, endive, lettuce (head), lettuce (leaf), marjoram, muskmelons, onions (dry bulb only), onions (green), peaches, sugar apple, summer squash, sweet potatoes, tangerines, tomatoes, turnip tops or turnip greens, and wheat. The required number and distribution of field trials for items in column A support items in column B for this situation. The minimum numbers of field trials for these commodities are specified in Table 1 or Attachment 7. [Note: Although ''muskmelons'', oriental radish, and ''summer squash'' do not appear by name in column B next to their entry in column A, for practical purposes theseentries are treated as falling under the situation described above with the numbers of field trials specified in Table 1.]

The second situation occurs in cases where the item in column A is a term identifying a group of commodities in column B. These include the following column A commodities: beans, beans (dry), beans (succulent), caneberries, cherries, citrus fruits, lettuce, melons, onions, peas, peas (dry), peas (succulent), peppers, and squash. Since these column A commodities are in essence crop ''groups'', the number of field trials required for these ''commodities'' will be determined in a similar manner as for crop subgroups (or crop groups in the case of citrus). Listed in Table 4 below are the field trial requirements to support a tolerance for these column A commodities. In each case, one or more representative commodities from column B are shown for which field trial data are required to support the ''commodity'' in column A. The required number of field trials for each representative commodity is also provided. Since these are treated similar to crop groups and/or subgroups, a 25% reduction in the required number of field trials for commodities typically requiring 8 or more field trials was employed in those case where there is more than one representative commodity.

Column A Commodities	Representative Column B Commodities	Acres (x1000)	% Consumption	Number of Field Trials if Not in Crop Group	Number of Field Trials if Part of Crop ''roup'' in Column A	Total Number of Required Field Trials for Tolerance on Crop ''Group'' in Column A
Beans	one edible podded bean	289	0.372	8	6	

Column A Commodities	Representative Column B Commodities	Acres (x1000)	% Consumption	Number of Field Trials if Not in Crop Group	Number of Field Trials if Part of Crop ''roup'' in Column A	Total Number of Required Field Trials for Tolerance on Crop ''Group'' in Column A
	one succulent shelled bean	51	0.048	8	6	
	one dried shelled bean	1750	0.267	12	9	
						12
Beans, dry	one dried shelled bean	1750	0.267	12	12	12
Beans, succulent	one succulent edible podded bean	289	0.372	8	6	
	one succulent shelled bean	51	0.048	8	6	
						12
Caneberries	any one blackberry or raspberry	23	0.024	3	5	5
Cherries	tart (sour) cherries	68.4	0.035	8	6	
	sweet cherries	60.5	0.031	8	6	
						12
Citrus fruits	See Table 2					23
Lettuce	lettuce, head	240	0.394	8	6	
	lettuce, leaf	51	0.025	8	6	
						12
Melons	cantaloupe	130	0.083	8	8	8
Onions	dry bulb onions	246	0.199	8	6	
	green onions	18.1	0.004	3	3	
						9
Peas	one edible podded pea	unknown	unknown	3	3	
	one succulent shelled pea	314	0.319	8	6	
	one dried shelled pea	395	0.005	5	5	
						14
Peas (dry)	one dried shelled pea	395	0.005	5	5	5

Column A Commodities	Representative Column B Commodities	Acres (x1000)	% Consumption	Number of Field Trials if Not in Crop Group	Number of Field Trials if Part of Crop ''roup'' in Column A	Total Number of Required Field Trials for Tolerance on Crop ''Group'' in Column A
Peas (succulent)	one edible podded pea	unknown	unknown	3	3	
	one succulent shelled pea	314	0.319	8	6	
						9
Peppers	peppers, bell	70.6	0.040	8	6	
	peppers, non-bell	27.7	0.016	3	3	
						9
Squash[1]	one variety summer squash	29.0	0.055	5	8	8

[1] To be consistent with the proposed squash/cucumber subgroup (see Table 3), one variety of summer squash was chosen as representative of all squash and pumpkins. However, since the combined acreage and consumption for all these commodities far exceeds that for the representative commodity, summer squash (combined acreage = 99,000 including 58,000 for summer and winter squash, and 41,000 for pumpkins; combined consumptions are 0.118% and 0.2% for the general population and non-nursing infants, respectively), the required number of field trials for the latter was increased one level from 5 to 8. Alternatively, five trials each could be conducted on summer squash and winter squash to obtain a tolerance on ''squash''.

Table 5.—Suggested Distribution of Field Trials By Region For Crops Requiring <3 Trials

Crop	Total No. of Trials[1]	Number of Trials in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Alfalfa	12	1	1			6	1	1	1	1				
	9	1				4	1	1	1	1				
Almonds	5					5								
Apples	16	4	2			3				1	1	5		
	12	3	1			2				1	1	4		
Apricots	5					4	1							
Asparagus	8		1			2					3	2		
	6		1			2					2	1		
Avocados	5			1							4			
Bananas	5			1										4
Barley	12	[2]1	[2]1			3		4	1	1		2		
	9	[2]1	[2]1			2		3		1	1	1		
Beans, Dried	12	1				5		2	1	1	1	1		
	9					4		1	1	1	1	1		

Table 5.—Suggested Distribution of Field Trials By Region For Crops Requiring <3 Trials—Continued

Crop	Total No. of Trials[1]	Number of Trials in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Beans, Lima, Succulent	8		4			1					2	1		
	6		3			1					1	1		
Beans, Snap	8	1	1	1		3					1	1		
	6	1	1	1		2						1		
Beets, Garden	5	1				2	1						1	
Blackberries[3]	5		1				1						3	
Blueberries	8	1	3			3							1	
	6	1	2			2							1	
Broccoli	8						1				6			
	6						1				4		1	
Buckwheat	5	1				1		3						
Cabbage	8	2	1	1		1	1		1		1			
	6	1	1	1		1	1				1			
Canola	8		1			2		2				3		
	6		1			2		1				2		
Cantaloupes	8		1			1	2				4			
	6		1			1	1				3			
Carrots	8			1		1	1				4	1		
	6			1		1	1				3			
Cauliflower	8	1				1					5		1	
	6	1				1					3		1	
Celery	8			2		1					5			
	6			1		1					4			
Cherries, Sour	8	1				5				1		[2]1	[2]1	
	6	1				4				1				
Cherries, Sweet	8					2					2	3	1	
	6					2					2	2		
Clover	12	1	1		1	3	1	1	1	1	1	1		
	9	1	1		1	2	1	1	1	[2]1	[2]1			
Coconut	5													5
Coffee	5													5
Collards	5		2	1			1				1			
Corn, Field	20	1	1			17	1							
	15	1	1			12	1							

Table 5.—Suggested Distribution of Field Trials By Region For Crops Requiring <3 Trials—Continued

Crop	Total No. of Trials[1]	Number of Trials in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Corn, Sweet	12	2	1	1		5					1	1	1	
	9	1	1	1		3					1	1	1	
Cotton	12		1		3		1		4		3			
	9		1		2		1		3		2			
Cranberries	5	2				2							1	
Cucumbers	8		3	1		2	1				1			
	6		2	1		2	1							
Flax	5					2		3						
Grapefruit	8			5			1				2			
	6			3			1				2			
Grapes	12	2									8	2		
	9	2									5	2		
Grasses (All Areas Across the Country)	12/9													
Lemons	5			1							4			
Lettuce, Head	8	[2]1	[2]1	1							6			
	6	[2]1	[2]1	1							4			
Lettuce, Leaf	8	[2]1	[2]1	1							6			
	6	[2]1	[2]1	1							4			
Mandarins (tangerines)	5			3							2			
Melons, Honeydew	5						1				4			
Millet, Proso	5					1		2	2					
Mint	5					2						3		
Mustard Greens[4]	8		2	1	1	1	1				2			
	5		1		1	1	1				1			
Nectarines	8	1	1								5	1		
	6	[2]1	[2]1								4	1		
Oats	16	1	1			9	1	3	1					
	12	1	1			6	1	2	1					
Okra	5		1	1	1		2							
Onions, Dry Bulb	8	1				1	1		1		2	1	1	
	6	1					1		1		2	1		
Oranges, Sour and Sweet	16			11			1				4			
	12			8			1				3			
Peaches	12	1	4		1	1	1				4			

Table 5.—Suggested Distribution of Field Trials By Region For Crops Requiring <3 Trials—Continued

Crop	Total No. of Trials[1]	Number of Trials in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
	9	1	3			1	1				3			
Peanuts	12		8	1			2		1					
	9		5	1			2		1					
Pears	8	1									3	4		
	6	1									2	3		
Peas, Garden, Succulent	8	[2]1	[2]1			4						2	1	
	6	[2]1	[2]1			3						1	1	
Pecans	5		2		1		1		1					
Peppers, Bell	8		2	2		1	1				2			
	6		1	1		1	1				2			
Pineapples	8													8
	6													6
Plums	8					1					5	1	1	
	6					1					4		1	
Potatoes	16	2	1	1		4				1	1	6		
	12	2	1	1		2				1	1	4		
Pumpkins	5	1	1			1	1				1			
Radish	5	1		2		1					1			
Raspberries, Black and Red[3]	5	1				1							3	
Rice	16				11	1	2				2			
	12				7	1	2				2			
Rice, Wild	5					4					1			
Rye	5		1			2		2						
Safflower	5							2			3			
Sorghum, Grain (milo)	12		1		1	4	2	1	3					
	9				1	3	2	1	2					
Soybeans (dried)	20		2		3	15								
	15		2		2	11								
Spinach	8	1	2				2			1	2			
	6	1	1				1			1	2			
Squash, Summer[5]	8	1	2	1		1	1				1	1		
	5	1	1	1		1					1			
Squash, Winter	5	1	1	1		1					1			
Strawberries	8	1	1	1		1					3		1	

Table 5.—Suggested Distribution of Field Trials By Region For Crops Requiring <3 Trials—Continued

Crop	Total No. of Trials[1]	Number of Trials in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
	6	1		1		1					2		1	
Sugar Beets	12					5		1	1	1	2	2		
	9					5		1	1		1	1		
Sugarcane	8			3	3		1							1
	6			3	2									1
Sunflowers	8					3		4	1					
	6					2		3	1					
Sweet Potatoes	8		4	1	1		1				1			
	6		3		1		1				1			
Tomatoes	16	1	1	2		1					11			
	12	1	1	2		1					7			
Turnip Roots	5		2			1	1				1			
Turnip Tops	5		2		1	1	1							
Watermelons	8		2	2		1	2				1			
	6		2	1		1	2				1			
Wheat	20		1		1	5	1	5	6			1		
	15		1		1	3	1	4	4			1		

[1] Where two entries are provided for a crop (with the exception of mustard greens and summer squash as explained below), the second is for situations where a 25% reduction in the number of trials is possible due to the crop being a representative commodity used to obtain a crop group tolerance or due to the pesticidal use resulting in no quantifiable residues.

[2] Either region is acceptable.

[3] A minimum of five trials is required on any one blackberry or any one raspberry if a tolerance is sought on ''caneberries'' (see Table 3 or Table 4). A minimum of three trials is needed if a tolerance is sought on only blackberries or only on raspberries.

[4] A minimum of eight trials is required on mustard greens if a tolerance is sought on the crop subgroup leafy Brassica greens (see Table 3). A minimum of five trials is required if a tolerance is sought on only mustard greens.

[5] A minimum of five trials is required for a tolerance on ''summer squash''. If a tolerance is sought on ''squash'', at least 8 trials are required on summer squash as a representative commodity (see Table 4). Alternatively, five trials each could be conducted on summer squash and winter squash to obtain a tolerance on ''squash''.

Table 6—Regional Distribution of Crop Production

Crop	Total % Production Accounted	Percentage of Crop Production (Acreage Basis) in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Alfalfa	99	8	3			51		14		13	4	6		
Almonds	100										100			
Apples	97	27	11			20				3	6	30		
Apricots	96										89	7		
Artichokes, globe	100										100			
Asparagus	97		3			28					38	28		
Avocados	100			9							91			
Bananas	99			<10										<90
Barley	99	2	2			29		36	2	6	3	19		
Beans, Dried	99	2				45		17	11	3	10	11		
Beans, Lima, Dried	99										97	2		
Beans, Lima, Succulent	97		46			12					28	11		
Beans, Mung	95						95							
Beans, Snap	97	14	16	9		45					3	10		
Beets, Garden	97	28	2			45	6				5		11	
Blackberries	95		7		3	6	6						73	
Blueberries[1]	94	11	36			40							7	
Bok choi	99		13	40							39			7
Boysenberries	99												99	
Broccoli	100						5				92		3	
Brussels sprouts	97	2									95			
Buckwheat	96	15				15		66						
Cabbage	93	21	16	11		18	12		3		12			
Cabbage, Chinese	97	5	8	34							46			4

Table 6—Regional Distribution of Crop Production—Continued

Crop	Total % Production Accounted	Percentage of Crop Production (Acreage Basis) in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Cacao Bean	100													100
Canola[2]	90		15			25		20				30		
Cantaloupes	95	2	5			6	23				59			
Carrots	98			10		13	9				59	5	2	
Cauliflower	97	4		2		4					77		10	
Celery	99			23		9	4				63			
Cherries, Sour	100	11				75				9		3	2	
Cherries, Sweet	98	4				20				4	22	39	9	
Coconut	100													100
Coffee	100													100
Collards	99	4	60	8	4	6	7				10			
Corn, Field	97	3	6			86	2							
Corn, Pop	95					91			4					
Corn, Sweet	96	13	4	8		50					3	11	7	
Cotton	97		8		26		11		37		15			
Cranberries	88	45				33							10	
Cucumber	94	3	36	10		27	10				5		3	
Currants	98												98	
Dates	100										100			
Eggplant	94	5	35	35	2	5					10			2
Endive (escarole)	96	5	13	66							12			
Figs	99										99			
Filbert/hazel nut	100												100	
Garlic	100									7	82	11		

Ginger	100													100
Grapefruit	100			73			13				14			
Grapes	96	5									86	5		
Guar	94								94					
Hops	94											94		
Kale	96	8	44	9	4	11	10				10			
Kiwi Fruits	99										99			
Kumquats	100			42							58			
Lemons	100			3							97			
Lentils	99						4				95			
Lettuce (head + leaf)	94	[3] 2	[3] 2	4							88			
Limes	99			80							19			
Loganberries	97												97	
Macadamia nut	100										3			97
Mandarins[4] (tangerines)	99			66							33			
Melons, honeydew	98						17				81			
Millet (proso millet)	99					29		35	35					
Mint	99					30						69		
Mustard Greens	97		24	5	12	15	20				21			
Nectarines	98	3	3								88	4		
Oats	97	8	2			61	3	20	3					
Okra	97		28	8	9		46				6			
Olives	100										100			
Onion, Dry Bulb	96	10	2			9	15		10	5	21	16	8	
Onions, Green	97	3	4			8	18		3		54	2	5	
Oranges, Sour and Sweet	100			72			2				26			

Table 6—Regional Distribution of Crop Production—Continued

Crop	Total % Production Accounted	Percentage of Crop Production (Acreage Basis) in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Papayas	96													96
Parsley	99	3	20	20		6	15				33			2
Pawpaws	100		100											
Peaches	97	7	39		3	9	6			2	29	2		
Peanuts	100		72	5			16		7					
Pears	95	7				2					33	53		
Peas, Austrian Winter	100											100		
Peas, Garden, Dried	97											97		
Peas, Garden, Succulent	92	5	4			49					3	22	9	
Pecans	100		35	3	8	2	34		10	2	6			
Peppers, Bell	92	4	20	25		10	8		2		23			
Peppers, Non-bell	94		4	3		4			50	15	18			
Persimmons	93			3							90			
Pimentos	92		86							6				
Pineapples	100													100
Pistachios	100										100			
Plantains	100													100
Plums	98					3					90	2	3	
Pomegranates	99										99			
Potatoes	95	11	4	3		27				7	4	39		
Pumpkins	86	20	12			39	5				10			
Quinces	100										100			
Radishes	96	2		67		21					6			
Raspberries, Black and Red	97	8				15							74	

Rhubarb	94					22							72	
Rice	100				70	3	13				15			
Rice, Wild	100					79					21			
Rye	97	4	13	2		32		42	4					
Safflower	97							44			53			
Sorghum, Grain (milo)	100		2		6	34	17	12	29					
Soybean (dried)	99		9		15	75								
Spinach	96	7	17		3	3	26			9	31			
Squash, Summer or Winter[5]	95	10	23	19	3	12	8				14	6		
Strawberries	99	9	6	11	2	10					43		18	
Sugar Beets	100					52		7	8	5	14	14		
Sugarcane	100			51	35		4							10
Sunflowers	100					35		58	7					
Sweet Potatoes	99		66	2	17		7				7			
Tangelos	100			61							39			
Tobacco	98		77			21								
Tomatoes	97	3	6	12		8					68			
Turnip roots	94	5	35	5	3	13	13				14	2	4	
Turnip tops	98		40	3	22	14	10		2		7			
Walnuts, Black and English	98										98			
Watermelons	94		21	19	5	8	21		7		13			
Wheat	94		4		4	23	6	26	26			5		

[1] Distribution of blueberry production based on tame (highbush) blueberries only.

[2] Approximate distribution of canola production based on 1993 acreage information provided by Intermountain Canola.

[3] Represents Regions 1 (NY) and 2 (NJ).

[4] Distribution of mandarin (tangerine) production based on acreage information for ‘‘honey tangerines’’ plus ‘‘other tangerines’’.

[5] Distributions of both summer squash and winter squash based on acreage information for ‘‘squash’’.

Attachment 8— Guidelines on Minimum Sample Sizes for Agricultural Commodities from Supervised Field Trials for Residues Analysis

CCPR 1987 ALINORM 87/24A APPENDIX IV ANNEX I

[''Provisionally Adopted'' by 19th CCPR ALINORM 87/24A para 251, 1987]

The 'Guidelines on pesticide residue trials to provide data for the registration of pesticides and the establishment of maximum residues limits'' include a section entitled ''Guide to Sampling'' in which minimum sample sizes are recommended for a number of crops, selected as examples. Practical experience in sampling in recent years has indicated the need to reconsider the recommendations in the Guidelines for the sample sizes and the ad hoc Working Group on the Development of Residues Data and Sampling recommends that the Annex II which follows this Annex I replaces the relevant section in the Trials Guidelines.

The major changes are the results of adopting a general principle that, with certain exceptions, such as very small items like berries, nuts, grain, and immature vegetables, it is more appropriate to recommend taking a number of crop units rather than a minimum weight. In many cases, the recommendation is to take 12 units for large items or 24 units for smaller items. The choice of 12 units permits easier planning of composite samples, for example, 3 units from each of 4 replicates (6 units for smaller items). It is useful, too, in sampling tree fruits, where 6 fruits from each of 4 trees is recommended. The principle of taking 12 units is readily extended to crops such as cereals, fodders, or grain where a minimum sample weight is proposed with sampling from 12 areas of the plot.

A number of crops can be harvested mechanically and in these cases 12 primary samples from the harvester as it proceeds through the treated plot is recommended.

Although it is not normally recommended it may sometimes be necessary to subsample bulky or heave items before shipment to the residue laboratory. This practice must be limited to special sampling problems identified in Annex II always bearing in mind the importance of maintaining a fully representative sub-sample and avoiding any possible contamination or deterioration of the material. It is essential that it should only be done if a clean area is available and if the personnel involved have received specific instruction or training in this respect.

The ad hoc Working party emphasized that the recommendations for minimum sizes are for samples of crops at the stage of growth at which they would be harvested for consumption when taken from supervised trials, which frequently involve relatively small plots. It may be necessary to take larger sample in certain circumstances, especially if larger plots or fields are being sampled. Larger samples of some crops may also be

needed if particularly low limits of determination are involved (thus possibly requiring larger analytical samples) or for multi-residue determinations (requiring larger, or multiple, analytical samples). The small sample size required by most analytical methods is not the major factor in deciding the size of field samples - obtaining representative material must be the priority in the field.

Alternative considerations may apply when deciding on the quantities of immature crops required from residue dissipation trials.

Sample Type	Codex Code No.	Previous Recommendation	New Recommendation
Fodder and sugar beets	VR 0596 AM 1051	5 kg (min 5 plants)	12 plants
Potatoes	VR 0589	5 kg or 5 items	24 tubers or 12 of very large from at least 6 plants
Other root crops, e.g., carrots, red beet, Jerusalem artichoke, sweet potato, celeriac, turnip, swede, parsnip, horseradish, salsify, chicory, radish, scorzonera.	Group 016	5 kg (large) 2 kg (small items).	12 large roots or 24 (or more) small for minimum sample weight of 2 kg
Leeks	VA 0384	2 kg	12 plants
Spring Onions	VA 0389	2 kg	24 plants (or more for a minimum sample weight of 2 kg
Garlic, shallots	VA 0381 VA 0388	2 kg	24 bulbs from at least 12 plants
Small-leaf salad crops, e.g., cress, dandelion, corn salad	Group 013	2 kg	0.5 kg from at least 12 plants (or sites in plot)
Spinach, chicory leaves	VL 0469 VL 0502 VL 0503	2 kg	1 kg from at least 12 plants
Lettuce	VL 0482 VL 0483	2 kg	12 plants or 1 kg from at least 12 plants if individual leaves are collected
Endive	VL 0476	2 kg	12 plants
Kale forage	AV 0480	5 kg	2 kg from at least 12 plants sampled from at least 2 levels on the plant
Kale	VL 0480		
Green cruciferous e.g., fodder crops, rape mustard, green oil poppy.	Group 023		2 kg from at least 12 separate areas of plot[(b)]
Large brassica crops e.g., cauliflower, cabbage	Group 010	5 kg or 5 items	12 plants
Brussels sprouts, Broccoli	Group 010	2 kg	1 kg from at least 12 plants and for Brussels sprouts sampled from at least 2 levels on the plant
Kohlrabi	VB 0405	5 kg or 5 items	12 plants
Celery	VS 0624	2 kg	12 plants
Rhubarb	VS 0627	2 kg	12 sticks (or more) from at least 12 separate plants for minimum sample weight of 2 kg
Asparagus	VS 0621	2 kg	24 sticks (or more) from at least 24 separate plants for minimum sample weight of 2 kg
Globe artichoke	VS 0620		12 heads
Soybeans	VS 0541	1 kg	1 kg from at least 12 separate areas of plot
Peas, Phaseolus beans (French, Kidney, Runner etc)	Group 014	2 kg	1 kg (fresh green or dry seed as appropriate)
broad beans, field beans, lentils	Group 015	2 kg	

Sample Type	Codex Code No.	Previous Recommendation	New Recommendation
Tomatoes, green peppers	Group 012	2 kg	24 fruits or 12 from large fruiting varieties from at least 12 plants (more if necessary for a minimum sample weight of 2 kg)
Aubergines (egg plants)	VO 0440	5 kg or 5 items	12 fruits from 12 separate plants
Cucumbers	VO 0424	5 kg or 5 items	12 fruits from 12 separate plants
Gherkins , courgettes squash	Group 011	2 kg	24 fruits from at least 12 plants (more if necessary to make a minimum weight of 2 kg)
Melons, gourds, pumpkins , water melons	Group 011	5 kg or 5 items	12 fruits from 12 separate plants
Sweet corn	VO 0447	2 kg	12 ears (more if necessary to make a minimum weight of 2 kg
Fruit			
Citrus fruit e.g., orange, lemon, clementine, mandarin, pomelo, grapefruit, tangelo, tangerine.	Group 001	5 kg	24 fruit from several places on at least 4 individual trees (more if necessary for a minimum sample weight of 2 kg
Pome fruit e.g., apples, pears, quinces, medlars	Group 002	5 kg	
Large stone fruit, e.g., apricots, nectarines, peaches, plums.	Group 003	5 kg (2 kg for plums)	
Small stone fruit	Group 003	2 kg	1 kg from several places on at least 4 trees
Grapes	FB 0269	2 kg	12 bunches, or parts of 12 bunches from separate vines to give at least 1 kg
Currants, raspberries and other small berries	Group 004	2 kg	0.5 kg from at least 12 separate areas of bushes
Strawberries, gooseberries	FB 0268 FB 0275 FB 0276	2 kg	1 kg from at least 12 separate areas of bushes
Miscellaneous, small fruits, e.g., olives, dates, figs	Group 005	2 kg	1 kg from several places on at least 4 trees
Bananas	Fl 0327	5 kg or 4 fruits from each of 5 bunches.	24 fruits from at least 6 bunches from separate trees and from several places of each of the bunches
Miscellaneous fruit e.g., avocados , guavas, mangoes, pawpaws, pomegranates, persimmons, kiwi fruit, litchi.	Group 006	5 kg	24 fruits from at least 4 separate trees or plants (more fruit if necessary for a minimum sample weight of 2 kg)
Pineapples	Fl 0353	5 kg or 5 items	12 fruit
Grain of wheat, barley, oats, rye, tritical e and other small grain cereals; maize (off the cob), rice, sorghum.	Group 020	1 kg (2 kg maize)	1 kg from at least 12 separate areas of a plot or treatment lot (applies to both field and post-harvest trials)
Straw of the above crops	Group 051	1 kg	0.5 kg from at least 12 separate areas of a plot[b]
Maize, straw/stover/ fodder (mature plants excluding cobs)	AF 0645	5 plants	12 plants[a]
Green or silage maize		5 plants	12 plants[a]
Green forage/silage crops of alfalfa, clover, fodder peas and beans, vetch, sainfoin, lotus, fodder soybeans, rye-grass, fodder cereals, sorghum.	Group 050	1 kg (smaller leaves) 2 kg (larger leaves).	1 kg from at least 12 separate areas of a plot
Dry hay of the above crops	Group 050	1-2 kg	0.5 kg from at least 12 separate areas of a plot[b]
Peanuts	SO 0697	1 kg (2 kg with fibre)	1 kg from at least 24 plants
Treenuts , Walnuts, chestnut s almonds, etc	Group 022	1 kg	1 kg (with or without shells)
Coconut	TN 0665	5 kg or 5 items	12 nuts
Rapeseed , flax and wild mustard	Group 023	1 kg	0.5 kg from at least 12 separate areas of a plot[b]
Sunflower, safflower	SO 0702	1 kg	21 heads or 1 kg from 12 separate areas of a plot[b]

Sample Type	Codex Code No.	Previous Recommendation	New Recommendation
Cottonseed	SO 0691	1 kg	12 heads or 1 kg with or without fibre
Coffee, cocoa	Group 024	2 kg	1 kg (fresh or dry)
Garden herbs and medicinal plants, e.g., parsley, thyme	Group 027 Group 028 Group 057.		0.5 kg fresh 0.2 kg dry
Tea (dry leaves)	Group 066	1 kg	0.2 kg
Mushrooms	VO 0450		12 items or more with a minimum sample weight of 0.5 kg
Sugarcane	GS 0659	5 kg (20 cm of stem)	12 × 20 cms lengths of stem from 12 areas of the plot[a]
Hops (dry cones)	DM 1100		0.5 kg
Beer, wine, cider, fruit juices	Group 070		1 litre

[a] Divide each stem with leaves attached into 3 equal lengths. Take top, middle and bottom portions respectively from each of three groups of four stems ensuring that parts of all 12 stems are included in the sample.
[b] Crops which are harvested mechanically can be sampled from the harvester as it proceeds through the crop.

Graphic is not available.

ATTACHMENT 10
REGIONAL MAP FOR TRIAL DISTRIBUTION

Border Definitions

I. ME, NH, VT, MA, RI, CT, NY, PA

NJ - N of Rt. 1

MD - NW of I-95

DVA - N of I-64 and W of I-81

WV - N of I-64 and E of I-77

II. NC, SC, GA, DE,

VA - E of I-81 or S of I-64

MD - SE of I-95

NJ - S of Rt. 1

WV - S of I-64

KY - S of I-64 and S of BGP and E of I-65

TN - E of I-65

AL - Except Mobile and Baldwin Co.'s

III. FL, AL, - Mobile and Baldwin Co.'s

IV. LA, AR, MS

TN - W of I-65

MO - E of Rt. 67 and S of Rt. 60

V. MI, IN, IL, WI, MN, IA,

OH - W of I-77

WV - N of I-64 and W of I-77

KY - N of I-64 or N of BGP or W of I-65

MO - W of Rt. 67 or N of Rt. 60

KS, NE, SD, ND - all E of Rt. 281

VI. OK - E of Rt. 281/183

TX - E of Rt. 283 or E of I-15

VII. MT - E of Rt. 87 or E of I-15

WY - E of I-25 or N of I-90

ND, SD, NE - all W of Rt. 281

VIII. KS - W of Rt. 281

Co - E of I-25

NM - E of I-25

TX - W or Rt 283 and NW of Rt. 377

OK - W of Rt. 281/183

IX. UT, NV,

NM - W of I-25 and N of I-10

CO - W of I-25

WY - W of I-25 and S of I-90

MT - W of Rt. 87 and W of I-15

AZ - NE of Rt. 89/93 and N of I-10

X. CA - Except Menocio, Humboldt, Trinity, Del Norte, and Siskiyou Co.'s

AZ - SW of Rt. 89/93 or S of I-10

NM - S of I-10

XI. ID

OR & WA - E of Cascades

XII. CA - Counties excluded from Reg. X

OR & WA - W of Cascades

XIII. HI,PR

ATTACHMENT 11

Number of Field Trials Required for Tolerances with Geographically Restricted Registration, and for 24(C) Special Local Needs Registrations

Throughout this guideline, additional guidance has been providedregarding field trial data requirements for tolerances withnational registrations. This attachment provides guidanceconcerning the number of field trials required for toleranceswith geographically restricted registrations, and 24(C) SpecialLocal Needs (SLN) registrations. Sampling requirements and othercriteria presented elsewhere in this guideline also apply to thedata requirements discussed in this attachment. A flow chartfollows the text below to facilitate determination of field trialdata requirements.

Tolerances with geographically restricted registrations may beestablished for minor agricultural uses (1990 Farm Bill). Specifically (see 7/7/93 memorandum, Victor J. Kimm, ActingAssistant Administrator, OPPTS, to Honorable Bob Graham, U.S.Senate),

> The Administrator shall not require a person to submit, in relation to registration or reregistration of a pesticide for minor agricultural use under this Act, any field residue data from a geographic area where the pesticide will not be registered for such use.

Comments below address the data requirements for both toleranceswith geographically restricted registration, and the additionalstate-specific data required for 24(C) SLN registrations. Whendiscussing the number of required field trials below, the term‘‘geographically restricted region’’ will apply to either of thesesituations.

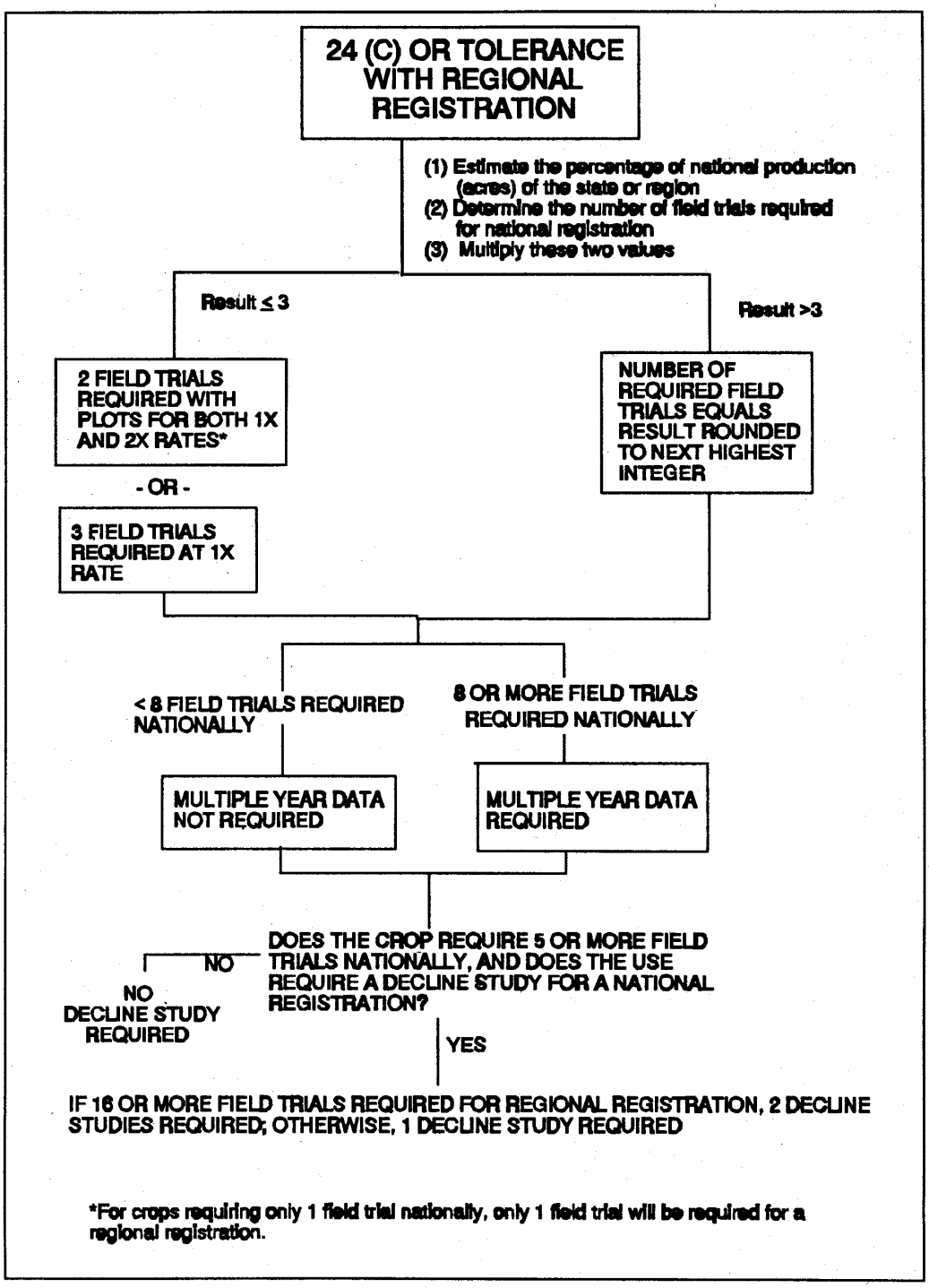
The number of field trials required for a tolerance withgeographically restricted registration is equal to the number offield trials required for the commodity for a national toleranceor registration, multiplied by the proportion (by acres) of thecrop grown in that region. However, regardless of the acreage inthe specific region for which the regional registration isrequested, at least 2 field trials will be required (except inthe case of very minor crops as specified elsewhere in thisdocument which require only 1 field trial for nationalregistration). Two composite samples per field trial aregenerally required. However, when 3 or fewer field trials arerequired for any registration, the registrant may choose to (a)obtain samples from 1X and 2X application rates from separateplots in each of 2 field trials (i.e., one composite sample takenfrom each of two 1X and two 2X separately treated plots,resulting in 4 total samples per field trial), or (b) perform 3field trials in different locations at the 1X rate (2 compositesamples obtained from each plot).

Field trial locations must be representative of growingconditions throughout the region covered by the regionalregistration.

For 24(C) SLN registrations requested for two neighboring states,data from one state will be accepted for a 24(C) use in aneighboring state only if (1) the states, or pertinent partsthereof, are in the same geographical region as defined in thisdocument, (2) a sufficient number of field trials are availablefrom the state to fulfill the requirements of the paragraph abovefor the acreage of commodity grown in both states, and (3) fieldtrials are performed in sufficiently diverse areas such thatconditions likely to be found in both states are represented inthe field trials.

For crops requiring 8 or more field trials nationally, regionaland 24(C) registrations will require multiple year field trialdata. Multiple year data are required to account for variabilitydue to varying climatic conditions and other factors which wouldnormally be expected to be seen by obtaining field trial datafrom more diverse regions, but would not be seen for regionalregistrations since field trial data are obtained from morelimited geographical areas. The total required number of fieldtrials must be performed over at least 2 different years (e.g.,if 4 total field trials are required, 2 would be performed in oneyear, and 2 in the next year). Multiple year data will not berequired if sufficient nationally representative or multiple yeardata are available for other pesticide formulations of the sameactive ingredient or similar uses from which the Agency canestimate likely variability.

For crops normally requiring 5 or more field trials for anational registration, *and uses requiring a decline study*(discussed elsewhere in this guidance), one or more declinestudies will be required for a 24(C) or regional registration. The number of decline studies required for a use will not exceedthe number required for a national tolerance/registration forthat commodity. See the flow chart for further details.



EXAMPLES

Example 1: A 24(C) SLN is desired for use of a pesticide on apples in Washington (WA). Since WA accounts for approximately 27% of national apple production, and since 16 field trials are required for apples nationally, 5 field trials will be required from WA for this use (0.27 x 16 = 4.3 or 5 field trials). Since greater than 8 field trials are required

nationally (16), multiple year data will be required (3 field trials the first year, 2 the second year). Finally, if the use were one requiring a decline study, 1 decline study would also be required for this 24(C) use.

Example 2: A 24(C) SLN is desired for use of a pesticide on alfalfa in Iowa (IA). Since IA accounts for approximately 8% of alfalfa grown nationally, and since 12 field trials are required for alfalfa nationally, 2 field trials will be required from IA to support this registration (0.08 x 12 = 0.96, however, except for crops requiring only 1 field trial nationally, at least 2 trials are required for any regional registration; therefore, 2 field trials are required). Since greater than 8 field trials are required nationally (12), the two required field trials would have to be distributed over two years (one field trial in each of two years). Since alfalfa requires greater than 5 field trials for a national registration (12), one of these studies would have to be a decline study if the use pattern requires a decline study. For the other study, one sample from each of 4 separately treated plots (two at 1X and two at 2X rates) would be required.

Example 3: A tolerance with regional registration is requested for application of a pesticide to peanuts in the Southeastern U.S. (GA, 42%, AL, 14%, NC, 9%, FL, 5%, SC, 1%, total 71% of U.S. peanut production). Since 12 field trial are required for peanuts nationally, 9 field trials would be required for this use (0.71 x 12 = 8.5 or 9 field trials required). Since 12 field trials are required nationally <8), the required field trials would have to be distributed over at least two years (preferably 5 the first year, four the second). If the use pattern was one requiring a decline study a single decline study would be required.